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TRANSCRIPT OF RECORD

SUPREME COURT OF THE UNITED STATES

OCTOBER TERM, 19[illegible]

No. 424

FEDERAL SECURITY ADMINISTRATOR,
PETITIONER

vs.

THE QUAKER OATS COMPANY

ON WRIT OF CERTIORARI TO THE UNITED STATES CIRCUIT COURT OF APPEALS FOR THE SEVENTH CIRCUIT

PETITION FOR CERTIORARI FILED SEPTEMBER 26, 1942
CERTIORARI GRANTED NOVEMBER 9, 1942

In the

United States Circuit Court of Appeals

For the Seventh Circuit

No. 7765

THE QUAKER OATS COMPANY,

Petitioner,

vs.

FEDERAL SECURITY ADMINISTRATOR,

Respondent.

Petition for Review of Order of the Federal Security Administrator.

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GOVERNMENT'S EXHIBIT NO. ONE.

Dated Aug. 1, 1940.

Federal Security Agency.

Food and Drug Administration.

[Docket No. F.D.C.-21]

Notice of Public Hearings for Purpose of Receiving Evidence Upon Basis of Which Regulations May Be Promulgated Fixing and Establishing a Definition and Standard of Identity for Each of the Following Foods: (A) Flour, White Flour, Wheat Flour, Plain Flour; (B) Durum Flour; (C) Whole Wheat Flour, Graham Flour, Entire Wheat Flour; (D) Cracked Wheat; (E) Crushed Wheat; (F) Whole Durum Wheat Flour; (G) Self-rising Flour, Self-rising White Flour, Self-rising Wheat Flour; (H) Phosphated Flour, Phosphated White Flour, Phosphated Wheat Flour; (I) Farina; and (J) Semolina.

Notice is given hereby that the Administrator of the Federal Security Agency, upon his own initiative and in accordance with the provisions of sections 401 and 701 (e) of the Federal Food, Drug, and Cosmetic Act, 52 Stat. 1046, 1055, 21 U.S.C. Secs. 341 and 371 (e) (Supp. V, 1939); the Reorganization Act of 1939, 53 Stat. 561, 5 U.S.C. Sec. 133 (Supp. V, 1939); and Reorganization Plans No. I (53 Stat. 1423, 4 F.R. 2727) and No. IV (54 Stat. ____, 5 F.R. 2421); will hold public hearings upon the proposals set forth herein, commencing at 10 o'clock in the morning of September 4th, 1940, in Rooms A, B, and C, Departmental Auditorium, Constitution Avenue, between 12th and 14th Streets NW., Washington, D. C., for the purpose of receiving evidence upon the basis of which regulations may be promulgated fixing and establishing a reasonable definition and standard of identity for each of the following foods: flour, white flour, wheat flour, plain flour; durum flour, whole wheat flour, graham flour, entire wheat flour; cracked wheat; crushed wheat; whole durum wheat flour; self-rising flour, self-rising white flour, self-rising wheat flour; phosphated flour, phosphated white flour, phosphated wheat flour; farina, and semolina.

All interested persons are invited to attend these hearings, either in person or by representative, and to offer evidence relevant and material thereto.

Mr. Alanson W. Willcox hereby is designated as presiding officer to conduct the hearings, in the place of the Administrator, with full authority to administer oaths and affirmations and to do all other things appropriate to the conduct of the hearings.

The hearings will be conducted in accordance with the rules of practice provided for such hearings, as published in the Federal Register of Wednesday, June 26, 1940, at pages 2379 to 2381 (5 F.R. 2379-2381).

In lieu of personal appearance, interested persons may offer affidavits by delivering the same to the presiding officer at Room 2240, South Building, Independence Avenue, between 12th and 14th Streets SW., Washington, D. C., on or before the date of the opening of the hearings. Such affidavits, if relevant and material, may be received and made a part of the record at the hearings, but the Administrator will consider the lack of oppertunity for cross-examination in determining the weight to be given to statements made in the form of affidavits. Every interested person will be permitted to examine the affidavits offered and to file counter-affidavits with the presiding officer.

The proposed definitions and standards of identity attached hereto and made a part hereof are subject to adoption, rejection, amendment, or modification by the Administrator, in whole or in part, as the evidence adduced at the hearings may require.

Done at Washington, D. C., this 1st day of August 1940.

Wayne Coy,
Acting Administrator,
Federal Security Agency.

§ 15.000. Flour, white flour, wheat flour, plain flour; identity; label statement of optional ingredients. (a) Flour, white flour, wheat flour, plain flour, is the food prepared by grinding and bolting cleaned wheat containing not more than 10 percent by weight of durum wheat, red durum wheat, or any mixture of these; such proportion of malted wheat may be used as compensates for any natural deficiency of enzymes. The final bolting is through a cloth having openings not larger than those of No. 100 woven wire cloth which complies with the specifications for

such cloth in "Standard Specifications for Sieves" published March 1, 1940, by the U. S. Department of Commerce, National Bureau of Standards. It is so freed from bran coats or germ, or both, that the percent of ash contained therein is not more than the sum of one-twentieth of the percent of protein contained therein and 0.3. Its moisture content is not more than 15 percent. Unless such addition conceals damage or inferiority of the flour or makes it appear better or of greater value than it is, one or any combination of two or more of the following optional bleaching ingredients may be added in a quantity not more than sufficient for bleaching, or in case such ingredient has an artificial aging effect, in a quantity not more than sufficient for bleaching and such artificial aging effect:

(1) Oxides of nitrogen.
(2) Chlorine.
(3) Nitrosyl chloride.
(4) Nitrogen trichloride.
(5) Benzoyl peroxide.

(b) When any optional bleaching ingredient is used, the label shall bear the word "Bleached". Wherever the name "Flour", "White Flour", "Wheat Flour", or "Plain Flour" appears on the label so conspicuously as to be easily seen under customary conditions of purchase, such word shall immediately and conspicuously precede or follow such name, without intervening written, printed, or graphic matter.

(c) For the purposes of this section—

(1) Ash content is determined by the method prescribed in the book "Official and Tentative Methods of Analysis of the Association of Official Agricultural Chemists", Fourth Edition, 1935, page 207, under "Method I—Official".

(2) Protein content is 5.7 times nitrogen content as determined by the method prescribed in such book on page 25, under "Kjeldahl-Gunning-Arnold Method—Official".

(3) Moisture content is determined by the method prescribed in such book on page 206, under "Vacuum Oven Method—Official".

(d) No provision of this section shall be construed as authorizing the addition of durum wheat, red durum wheat, or any mixture of these to other wheat used in preparing flour.

§ 15.010. Durum flour, identity. (a) Durum flour is the food prepared by grinding and bolting cleaned durum wheat containing not more than 10 percent by weight of wheat other than durum. The final bolting is through a cloth having openings not larger than those of No. 100 woven wire cloth which complies with the specifications for such cloth set forth in "Standard Specifications for Sieves" published March 1, 1940, by U. S. Department of Commerce, National Bureau of Standards. It is so freed from bran coats or germ, or both, that its ash content is not more than ..... per cent (to be fixed within the range of 1.2 percent to 1.5 percent). Its moisture content is not more than 15 percent.

(b) For the purposes of this section—

(1) Ash content is determined by the method prescribed in the book "Official and Tentative Methods of Analysis of the Association of Official Agricultural Chemists", Fourth Edition, 1935, page 207, under "Method I—Official",

(2) Moisture content is determined by the method prescribed in such book on page 206, under "Vacuum Oven Method—Official".

(c) No provision of this section shall be construed as authorizing the addition of wheat other than durum to durum wheat used in preparing durum flour.

§ 15.020. Whole wheat flour, graham flour, entire wheat flour, identity. (a) Whole wheat flour, graham flour, entire wheat flour, is the food prepared by so grinding cleaned wheat containing not more than 10 percent by weight of durum wheat, red durum wheat, or any mixture of these, that when tested by the method prescribed in subjection (b) (2) not more than 10 percent fails to pass through a No. 8 sieve and not less than 50 percent passes through a No. 20 sieve. The proportions of the natural constituents of such wheat, other than moisture, remain unaltered. Whole wheat flour contains not more than 15 percent of moisture.

(b) For the purposes of this section—

(1) Moisture is determined by the method prescribed in "Official and Tentative Methods of Analysis of the Association of Official Agricultural Chemists", Fourth Edition, 1935, page 206, under "Vacuum Oven Method—Official".

(2) The method referred to in subsection (a) is as

follows: Use No. 8 and No. 20 sieves, having standard 8 inch full height frames, complying with the specifications for wire cloth and sieve frames in "Standard Specifications for Sieves" published March 1, 1940, by U. S. Department of Commerce, National Bureau of Standards. Fit a No. 8 sieve into a No. 20 sieve. Attach bottom pan to the No. 20 sieve. Pour 100 grams of the sample into the No. 8 sieve. Attach cover and hold the assembly in a slightly inclined position with one hand. Shake the sieves by striking the sides against the other hand with an upward stroke, at the rate of about 150 times per minute. Turn the sieves about one-sixth of a revolution, each time in the same direction, after each 25 strokes. Continue shaking for two minutes. Weigh the material which fails to pass through the No. 8 sieve and the material which passes through the No. 20 sieve. Record percent by weight of each such material.

(c) No provision of this section shall be construed as authorizing the addition of durum wheat, red durum wheat, or any mixture of these to other wheat used in preparing whole wheat flour.

§ 15.030. Cracked wheat; identity. (a) Cracked wheat is the food prepared by so cracking to angular fragments cleaned wheat containing not more than 10 percent by weight of durum wheat, red durum wheat, or any mixture of these, that when tested by the method prescribed in § 15.020 (b) (2) not more than 10 percent fails to pass through a No. 8 sieve and not more than 10 percent passes through a No. 20 sieve. The proportions of the natural constituents of such wheat, other than moisture, remain unaltered. Cracked wheat contains not more than 15 percent of moisture as determined by the method prescribed in "Official and Tentative Methods of Analysis of the Association of Official Agricultural Chemists", Fourth Edition, 1935, page 335, paragraph 1, "Preparation of Sample—Official" and paragraph 2, "Moisture I Drying with Heat—Official".

(b) No provision of this section shall be construed as authorizing the addition of durum wheat, red durum wheat, or any mixture of these to other wheat used in preparing cracked wheat.

§ 15.040. Crushed wheat, identity. (a) Crushed wheat is the food prepared by so crushing cleaned wheat containing not more than 10 percent by weight of durum wheat,

red durum wheat, or any mixture of these, that when tested by the method prescribed in § 15.020 (b) (2) more than 10 percent fails to pass through a No. 8 sieve and less than 50 percent but more than 10 percent passes through a No. 20 sieve. The proportions of the natural constituents of such wheat, other than moisture, remain unaltered. Crushed wheat contains not more than 15 percent of moisture as determined by the method prescribed in "Official and Tentative Methods of Analysis of the Association of Official Agricultural Chemists," Fourth Edition, 1935, page 335, under paragraph 1, "Preparation of Sample—Official" and paragraph 2, "Moisture I Drying with Heat—Official."

(b) No provision of this section shall be construed as authorizing the addition of durum wheat, red durum wheat, or any mixture of these to other wheat used in preparing crushed wheat.

§ 15.050. Whole durum wheat flour, identity. (a) Whole durum wheat flour is the food prepared by so grinding cleaned durum wheat containing not more than 10 percent by weight of wheat other than durum, that when tested by the method prescribed in § 15.020 (b) (2) not more than 10 percent fails to pass through a No. 8 sieve and not less than 50 percent passes through a No. 20 sieve. The proportions of the natural constituents of such wheat, other than moisture, remain unaltered. Whole durum wheat flour contains not more than 15 percent of moisture as determined by the method prescribed in "Official and Tentative Methods of Analysis of the Association of Official Agricultural Chemists", Fourth Edition, 1935, page 206, under "Vacuum Oven Method—Official".

(b) No provision of this section shall be construed as authorizing the addition of wheat other than durum to the durum wheat used in preparing whole durum wheat flour.

§ 15.060. Self-rising flour, self-rising white flour, self-rising wheat flour; identity; label statement of optional ingredients. (a) Self-rising flour, self-rising white flour, self-rising wheat flour, is an intimate mixture of flour, sodium bicarbonate, and mono-calcium phosphate. It may be seasoned with salt. When tested by the method prescribed in subsection (c) it yields not less than _____ percent (to be fixed within the range of 0.5 percent to 0.7 percent) of carbon dioxide. The weight of sodium bicarbonate used is not more than four-fifths of the weight of

mono-calcium phosphate used; the sum of such weights is not more than ..... parts by weight (to be fixed within the range of 3.5 parts to 5.0 parts) for each 100 parts by weight of flour used. Subject to the conditions and restrictions prescribed by § 15.000 (a), the bleaching ingredients specified in such section may be added as optional ingredients. If the flour used in making the self-rising flour is bleached, the optional bleaching ingredient used therein (see § 15.000 (a)) is also an optional ingredient of the self-rising flour.

(b) When any optional bleaching ingredient is used, the label shall bear the word "Bleached". Wherever the name "Self-rising Flour", "Self-rising White Flour", or "Self-rising Wheat Flour" appears on the label so conspicuously as to be easily seen under customary conditions of purchase, such word shall immediately and conspicuously precede or follow such name, without intervening written, printed, or graphic matter.

(c) The method referred to in subsection (a) is the method prescribed in "Official and Tentative Methods of Analysis of the Association of Official Agricultural Chemists", Fourth Edition, 1935, beginning on page 184, under "Gasometric Method Using Chittick's Apparatus —Official", except that the following procedure is substituted for the procedure specified therein under "6—Determination."

Weigh 17 grams of the official sample into flask A, add 15-20 glass beads (4-6 mm, diameter) and connect this flask with the apparatus (fig. 19). Open stop-cock C and by means of the leveling bulb E bring the displacement solution to the 25 cc. graduation above the zero mark. (This 25 cc. is a partial allowance for the volume of acid to be used in the decomposition). Allow the apparatus to stand 1-2 minutes to insure that the temperature and pressure within the apparatus are the same as those of the room. Close the stopcock, lower the leveling bulb somewhat to reduce the pressure within the apparatus, and slowly run into the decomposition flask from burette F, 45 cc. of sulphuric acid (1+5). To prevent the liberated carbon dioxide from escaping through the acid burette into the air, keep the displacement solution in the leveling bulb at all times during the decomposition at a lower level than that in the gas-measuring tube. Rotate and then vigorously agitate the decomposition flask for three min-

utes to mix the contents intimately. Allow to stand for ten minutes to bring to equilibrium. Equalize the pressure in the measuring tube by means of the leveling bulb and read the volume of gas from the zero point on the tube. Deduct 20 cc. from this reading (this 20 cc. together with previous allowance of 25 cc. compensates for the 45 cc. acid used in the decomposition). Observe the temperature of the air surrounding the apparatus and also the barometric pressure and multiply the number of cc. of gas evolved by the factor given in Table 24—Chapter XLII for the temperature and pressure observed. Divide the corrected reading by 100 to obtain the apparent percent by weight of carbon dioxide in the official sample.

Correct the apparent percent of carbon dioxide to compensate for varying atmospheric conditions by immediately assaying a synthetic sample by the same method in the same apparatus.

The synthetic sample is prepared with 16.2 grams of flour, 0.30 gram of mono-calcium phosphate, 0.30 gram of salt, and a sufficient quantity of Sodium Bicarbonate U. S. P. (dried over sulphuric acid) to yield the amount of carbon dioxide recovered in assay of official sample. This quantity is determined by multiplying weight of carbon dioxide recovered in assay of official sample by 1.91.

The weight of carbon dioxide recovered from synthetic sample is divided by weight of carbon dioxide contained in sodium bicarbonate used and quotient recorded.

The apparent percent of carbon dioxide in official sample is divided by this quotient to obtain percent carbon dioxide in official sample.

§ 15.070. Phosphated flour, phosphated white flour, phosphated wheat flour; identity; label statement of optional ingredients. (a) Phosphated flour, phosphated white flour, phosphated wheat flour, is an intimate mixture of flour and not less than ____ percent (to be fixed within the range of 0.25 percent to 0.5 percent), but not more than ____ percent (to be fixed within the range of 0.75 percent to 1.0 percent), of mono-calcium phosphate. Subject to the conditions and restrictions prescribed by § 15.000 (a), the bleaching ingredients specified in such section may be added as optional ingredients. If the flour used in making the phosphated flour is bleached, the optional bleaching ingredient used there (see § 15.000 (a)) is also an optional ingredient of the phosphated flour.

(b) When an optional bleaching ingredient is used, the label shall bear the word "Bleached". Wherever the name "Phosphated Flour", "Phosphated White Flour", or "Phosphated Wheat Flour" appears on the label so conspicuously as to be easily seen under customary conditions of purchase, such word shall immediately and conspicuously precede or follow such name, without intervening written, printed, or graphic matter.

§ 15.080. Farina; identity. (a) Farina is the food prepared by grinding and bolting cleaned wheat containing not more than 10 percent by weight of durum wheat, red durum wheat, or any mixture of these. It is ground to such fineness that when tested by the method prescribed in subsection (b) (2) it passes through a No. 20 sieve but not more than ..... percent (to be fixed within the range of 1 percent to 3 percent) passes through a No. 100 sieve. It is so freed from bran coats or germ, or both, that its ash content is not more than ..... percent (to be fixed within the range of 0.45 percent to 0.65 percent). Its moisture content is not more than 15 percent.

(b) For the purposes of this section—

(1) Ash content is determined by the method prescribed on page 207, under "Method I—Official", and moisture content by the method prescribed on page 206, under "Vacuum Oven Method—Official", of "Official and Tentative Methods of Analysis of the Association of Official Agricultural Chemists", Fourth Edition, 1935.

(2) The method referred to in subsection (a) is as follows: Use No. 20 and No. 100 sieves, having standard 8 inch full height frames, complying with the specifications for wire cloth and sieve frames in "Standard Specifications for Sieves" published March 1, 1940, by U. S. Department of Commerce, National Bureau of Standards. Fit a No. 20 sieve into a No. 100 sieve. Attach bottom pan to the No. 100 sieve. Pour 100 grams of the sample into the No. 20 sieve. Attach cover and hold the assembly in a slightly inclined position with one hand. Shake the sieves by striking the sides against the other hand with an upward stroke, at the rate of about 150 times per minute. Turn the sieves about one-sixth of a revolution, each time in the same direction, after each 25 strokes. Continue shaking for two minutes. Weigh the material which fails to pass through the No. 20 sieve and the material which passes through the No. 100 sieve. Record percent by weight of each such material.

(c) No provision of this section shall be construed as authorizing the addition of durum wheat, red durum wheat, or any mixture of these to other wheat used in preparing farina.

§ 15.090. Semolina; identity. (a) Semolina is the food prepared by grinding and bolting cleaned durum wheat containing not more than 10 percent by weight of wheat other than durum. It is ground to such fineness that when tested by the method prescribed in § 15.080 (b) (2) it passes through a No. 20 sieve but not more than _____ percent (to be fixed within the range of 1 percent to 3 percent) passes through a No. 100 sieve. It is so freed from bran coats or germ, or both, that its ash content is not more than _____ percent (to be fixed within the range of 0.65 percent to 0.85 percent). Its moisture content is not more than 15 percent.

(b) For the purposes of this section—

Ash content is determined by the method prescribed on page 207, under "Method I—Official," and moisture content by the method prescribed on page 206, under "Vacuum Oven Method Official," of "Official and Tentative Methods of Analysis of the Association of Official Agricultural Chemists," Fourth Edition, 1935.

(c) No provision of this section shall be construed as authorizing the addition of wheat other than durum to durum wheat used in preparing semolina.

[F. R. Doc. 40-3196; Filed, August 2, 1940; 10:03 a. m.]

GOVERNMENT'S EXHIBIT NO. 2. Dated Aug. 7, 1940.

Federal Security Agency.

Food and Drug Administration.

[Docket No. F.D.C.—21.]

Postponement of the Opening of the Public Hearings to Be Held for the Purpose of Receiving Evidence Upon the Basis of Which Regulations May Be Promulgated Fixing and Establishing a Definition and Standard of Identity for Each of the Following Foods: (A) Flour, White Flour, Wheat Flour, Plain Flour; (B) Durum Flour; (C) Whole Wheat Flour, Graham Flour, Entire Wheat Flour; (D) Cracked Wheat; (E) Crushed Wheat; (F) Whole Durum Wheat Flour; (G) Self-rising Flour; Self-rising White Flour, Self-rising Wheat Flour; (H) Phosphated Flour, Phosphated White Flour, Phosphated Wheat Flour; (I) Farina; and (J) Semolina.

The public hearings announced for the purpose of receiving evidence upon the basis of which regulations may be promulgated, fixing and establishing a definition and standard of identity for flour and the related food products specified in the caption hereof, scheduled to commence on September 4, 1940 (5 Federal Register 2746-2749), are postponed hereby so that the hearings will be held commencing at 10 o'clock in the morning of September 9, 1940, in Rooms A, B, and C, Departmental Auditorium, Constitution Avenue, between 12th and 14th Streets NW., Washington, D. C.

The notice of hearings published in the Federal Register for August 3, 1940 (5 Federal Register 2746-2749), is adopted hereby and made a part hereof for all purposes, except that the date for the opening of the hearings will be September 9, 1940, instead of September 4, 1940. No other change in the notice of public hearings is made by this notice of postponement.

Done at Washington, D. C., this 7th day of August, 1940.

Paul V. McNutt,
Administrator.

[F. R. Doc. 40—3304; Filed, August 8, 1940; 12:31 p. m.]

Dated Oct. 10, 1940.

[Docket No. F.D.C. 21.]

In the Matter of a Definition and Standard of Identity for Each of the Following Foods: (A) Flour, White Flour, Wheat Flour, Plain Flour; (B) Durum Flour; (C) Whole Wheat Flour, Graham Flour, Entire Wheat Flour; (D) Cracked Wheat; (E) Crushed Wheat; (F) Whole Durum Wheat Flour; (G) Self-Rising Flour, Self-Rising White Flour, Self-Rising Wheat Flour; (H) Phosphated Flour, Phosphated White Flour, Phosphated Wheat Flour; (I) Farina; and (J) Semolina.

Notice of Reconvention of Hearings.

Notice is given hereby that the hearings in the above styled and numbered proceeding will be reconvened on November 12, 1940, at 10 o'clock in the morning, in Room 3106, South Building, United States Department of Agriculture, Independence Avenue, between 12th and 14th Streets SW., Washington, D. C., in accordance with the announcement of the Presiding Officer made at the original hearings herein which commenced on September 9, 1940.

Pursuant to the Presiding Officer's announcement, the reconvened hearings will be held for the purpose of receiving additional evidence relevant to the propriety of the addition of vitamins and minerals to the foods described in the original notice of hearings (5 F.R. 2746-2749) as (A) Flour; (G) Self-rising flour; (H) Phosphated flour; (I) Farina; and (J) Semolina. Additional evidence also will be received relative to the names of the foods containing such additions, and relative to the designation of the optional ingredients which shall be named on the label.

All interested persons are invited to attend these reconvened hearings, either in person or by representative, and to offer evidence relevant and material therein.

The hearings will be conducted in accordance with the procedure referred to in the original notice of hearings published in the Federal Register of August 3, 1940, at pages 2746 and 2749, inclusive (5 F.R. 2746-2749).

Alanson W. Willcox,
Presiding Officer.

[F. R. Doc. 40—4279; Filed, October 10, 1940; 11:12 a. m.]

9 PROCEEDINGS.

Presiding Officer Willcox: I will declare the hearing open.

First we will answer the reporters.

(Whereupon H. B. Alderson and R. J. Murray were duly sworn as official reporters.)

Presiding Officer Willcox: This proceeding is held under the authority of Sections 401 and 701 (e) of the Federal Food, Drug and Cosmetic Act, upon a proposal to issue a regulation fixing and establishing a definition and standard of identity for each of the foods mentioned in the notice of hearing.

The Federal Security Administrator is authorized by Section 401 to issue such a regulation if in his judgment such action will promote honesty and fair dealing in the interests of consumers. Section 701(e) requires that such a regulation be based upon evidence adduced at a public hearing.

On August 1, 1940, the Federal Security Administrator, upon his own initiative, gave notice of public hearings on proposals to establish definitions and standards of identity for the following foods:

(A) Flour, White Flour, Wheat Flour, plain Flour;

(B) Durum Flour;

(C) Whole Wheat Flour, Graham Flour, Entire 10 Wheat Flour;

(D) Cracked Wheat;

(E) Crushed Wheat;

(F) Whole Durum Wheat Flour;

(G) Self-rising Flour, Self-rising White Flour, Self-rising Wheat Flour;

(H) Phosphated Flour, Phosphated White Flour, Phosphated Wheat Flour;

(I) Farina, and

(J) Semolina.

The notice of hearings, with the proposals subjoined thereto and incorporated therein by reference, was published in the Federal Register for August 3, 1940. It specified the time and place for such hearings as 10 o'clock in the morning of September 4, 1940, in Rooms A, B, and C, Departmental Auditorium, Washington, D. C. Subsequently, on August 7, 1940, the Administrator, by an order appearing in the Federal Register for August 9, 1940, postponed the opening of the hearing to this time.

Copies of these two issues of the Federal Register have been distributed and there are additional copies available here if anyone does not have one.

In accordance with the applicable rules of practice, I now file, as an exhibit for the record, five copies of the
11 issue of the Federal Register containing the notice of hearing and the designation of Alanson W. Willcox—that is, myself, as presiding officer, to conduct the hearings in the place of the Administrator.

(The documents above referred to were received in evidence as GOVERMENT'S EXHIBIT NO. 1.)

I also file, and receive in evidence, five copies of the issue of the Federal Register containing the notice of postponement.

(The documents above referred to were received in evidence as GOVERNMENT'S EXHIBIT NO. 2.)

I call particular attention to the paragraph in the notice of hearing to the effect that the proposed definitions and standards of identity are subject to adoption, rejection, amendment or modification, in whole or in part, as the evidence adduced may require. Not only is the Administrator not bound to adopt the proposals as written, but he is not authorized to do so unless there is substantial evidence of record at the hearings to support the proposals. The Food and Drug Administration, I assume, will present evidence tending to show the reasonableness of the proposals and to show that their promulgation as regulations will promote honesty and fair dealing in the interest of consumers. Other interested persons will be allowed to examine the Government's witnesses, and to present such evidence as they desi[illegible] bearing on the desirability, for
12 these purposes, of a definition and standard of identity for the food products in question, and on the provisions which should be incorporated in such definitions and standards.

Every person that desires to participate in the hearings is required to file a written appearance setting forth his name, address, occupation, and representative capacity, if any. Forms for the notation of appearances have already been distributed and there are additional copies available if anyone has not received one.

Both in asking questions and in offering evidence you must identify yourselves so that the reporter may make the record complete.

In testifying, please avoid statements of conclusion and

law and only give the facts upon which you rely. A person testifying as an expert must state his qualifications in order that it may be determined, first, whether he is an expert, and second, how much weight should be given to his testimony.

The proceeding will be conducted in accordance with the rules of practice provided for such hearings, as promulgated by an order of the Secretary of Agriculture dated June 25, 1940, and appearing in the Federal Register for June 26, 1940. Those rules, copies of which are available at this desk, provide generally that the hearings are to be conducted in an informal but orderly manner,
13 in accordance with specific rules and, where such rules are inapplicable, incomplete, or inappropriate, in accordance with the directions of the presiding officer.

The rules provide that the evidence bearing on the proposal in general shall be given first, and thereafter the evidence with respect to the specific terms of the proposal, section by section. This order will be followed except as may be otherwise determined by the presiding officer. In each instance the Government witness will be heard first, trade testimony will be received next, and consumers and any other interested persons will be heard last.

No affidavits have been filed with the presiding officer to this proceeding, and in accordance with the regulations today, this is the last day for filing affidavits.

14 The Government requests the presiding officer to permit a slight deviation from the established order of procedure, and you will note that the rules of practice provide that the first part be evidence concerning the proposal in general and one of the categories there is the effect of the proposal. We ask that you allow us to introduce evidence as to the probable effect of the proposal, at the close of our evidence under each section. We will concern ourselves first with the presentation of evidence on the proposals in general, and after that we will take up each section and consider the section separately. The Government evidence will come in first, and then the trade evidence come in and then the consumer evidence, if any.

We will not attempt, with the permission of the presiding officer, of course, to build a separate and complete record under each section of the proposal. The rec-
15 ord will be complete in the sense that nothing will be done unless supported by substantial evidence of rec-

ord at the hearing, with some exceptions in the form of interpreting regulations which will be pointed out during the course of the hearing, but there will not be a separate record opened and closed under each section. To the extent that the sections are taken up and considered section by section, however, there will be separate records, and anyone desiring to buy a part of the transcript only, will not have any difficulty in determining which part he desires. The reporter can tell you and I am sure that you will not have any trouble with that.

Presiding Officer Willcox: Is there any objection to proceeding as suggested by Government counsel?

Mr. Campbell: I wonder if I understand that. Instead of the Government putting on its testimony as to each section, and then the other trade and the consumers—

Mr. Goodrich: No sir, the Government will put on its evidence under each section and then the trade put on its evidence under each section, and then the consumers, and the only point made is that the first part of the evidence will be general, will concern itself with the entire proposal, and the groundwork that has been done in the formulation of the statements, and each section will then be taken up and the order will be as I have suggested.

16 Presiding Officer Willcox: There are two proposals made, as I understand it. One is that there should not be a separate and complete record relating to each of the sections; the other being that the effect of the proposed regulation will be dealt with, not in the general testimony at the beginning of the hearing, but after the testimony specifically related to each section, is that right?

Mr. Goodrich: Yes.

Presiding Officer Willcox: Is there any objection to either of those variations?

If there are variations, will you bring them up?

17 JOSEPH CALLAWAY, JR., was called as a witness for and on behalf of the Food and Drug Administration, and having been first duly sworn, was examined and testified as follows:

Direct Examination by Mr. Goodrich.

Q. State your name and address, please, sir.

A. Joseph Callaway, Jr., Alexandria, Virginia.

Q. What is your present occupation or profession?

A. I am a chemist engaged in work having to do with the enforcement of the Food, Drug, and Cosmetic Act.

Q. And you are employed by the Food and Drug Administration, of the Federal Security Agency?

A. Yes, sir.

Q. In Washington, D. C.?

A. Yes, sir.

Q. In what capacity are you so employed?

A. As a senior chemist and Secretary of the Food Standards Committee of the Food and Drug Administration.

18 Q. Outline as briefly as possible your educational attainments and practical experience in the fields of chemistry and foods with special reference to those attainments and experience which qualify you to testify at this hearing.

A. I was graduated from the Alabama Polytechnic Institute, Auburn, Alabama, with degree of Bachelor of Science in Chemistry, in 1912. I received degree of Master of Science from the same institution in 1917. I carried on graduate work in chemistry of fermentation at the Pasteur Institute in Paris in 1919 and graduate work in organic and physical chemistry at Columbia University in 1928.

After graduation in 1912 I spent a short time in commercial work and as assistant in the Alabama State Laboratory. I then entered the service of the Bureau of Chemistry of the U. S. Department of Agriculture as Junior Chemist in 1914. I have been continuously in the service of the Bureau of Chemistry and its successor, the Food and Drug Administration, since that time, with the exception of two years in the army, from 1917 to 1919. I have been engaged in various activities consisting of laboratory and field work on food and drugs, beginning at headquarters in Washington, then at the field station in Buffalo, New York, later at Savannah, Georgia, and later at New York.

19 In 1929 I was made Chief of the New York Station of the Food and Drug Administration; in 1934 was transferred to Baltimore as Chief of that Station; later in the same year I was made Chief Chemist of the Eastern District and in 1938 was transferred to Washington to serve as Secretary of the Food Standards Committee.

As Chief of the New York and Baltimore Stations I directed the work of chemists and inspectors engaged in enforcement of the Food and Drugs Act of 1906. As Chief

Chemist of the Eastern District I supervised and participated in the work being done by all the chemists at the various stations in the Eastern District in connection with enforcement of the Food and Drugs Act of 1906. This District comprises all the states along the Atlantic Seaboard. Among other things I have examined samples of various flours in the laboratory, I have visited flour mills for purposes of securing information as to methods of manufacture, and so forth, and have directed enforcement work on flours believed to be in violation of the Food and Drugs Act.

During the many years spent in law enforcement work I have observed the promulgation of various standards and tolerances affecting various foods and have observed the changes in composition and methods of handling of such foods resulting from their standardization. I have received and investigated complaints from trade and con-
20 sumer sources as to various practices with respect to foods which would adversely affect consumer interest. I am in general acquainted with the results of enforcement of the Food and Drugs Act of 1906 and the Federal Food, Drug, and Cosmetic Act of 1938 up until the present time.

Q. Explain what the Food Standards Committee is, what its background is, what its functions are, what its position is with respect to definitions and standard of identity for foods as those standards are promulgated under the Federal Food, Drug and Cosmetic Act.

A. The Food Standards Committee is a committee created in the Food and Drug Administration to act in an advisory capacity in matters relating to formulation of proposed standards for foods. There have been various committees serving in related ways since 1902, with the exception of the period from 1907 to 1913. The first committee was created by the Association of Official Agricultural Chemists and collaborated with the Bureau of Chemistry of the U. S. Department of Agriculture in formulation of its first food standards. In 1913 there was created by the Secretary of Agriculture a committee known as the Joint Committee on Definitions and Standards, consisting of members of the Bureau of Chemistry, the Association of Official Agricultural Chemists, and the Association of American Dairy, Food, and Drug Officials.

21 This committee, with various changes of personnel, functioned from 1913 until 1937. The present commit-

tee was created to serve in connection with promulgation of standards under the Food, Drug, and Cosmetic Act. It consists of six members, two from the Food and Drug Administration and four State Officials, two representing the Association of Official Agricultural Chemists, and two the Association of American Dairy, Food, and Drug Officials. The committee meets at the call of the Chief of the Food and Drug Administration. It studies questions relating to standards for foods submitted to it, holds informal hearings for the purpose of receiving suggestions and recommendations from trade and consumer sources, and makes recommendations to the Food and Drug Administration.

Q. What duties do you perform as Secretary of the Food Standards Committee?

A. In connection with my duties as Secretary of the Food Standards Committee I collect, summarize, and tabulate information and analytical data dealing with methods of manufacture and composition of various foods being studied with view to their standardization.

Q. Are you familiar with Federal food standards making in general?

A. Yes.

Q. Tell us, if you will, of food standards making 22 in the past.

A. Prior to passage of the Food, Drug, and Cosmetic Act standards had been formulated for a large number of foods. This work was begun about 1903 when Congress authorized the Secretary of Agriculture to promulgate standards of purity for foods. This authority continued until June 30, 1906. The Secretary of Agriculture, through the Bureau of Chemistry of the U. S. Department of Agriculture, collaborated with the Association of Official Agricultural Chemists who were probably the first organization to study standard making based on the objective examination of foods. After June 30, 1906, no legal authority existed for promulgating food standards. Some kind of standards, however, were so badly needed in connection with the enforcement of the Food and Drugs Act of 1906 and various similar State laws that in 1913, as I have described in connection with the Food Standards Committee, the Secretary of Agriculture created the Joint Committee on Definitions and Standards for the purpose of formulating standards of purity for foods. Most of the standards recommended by this committee were promul-

gated by the Secretary as "Advisory Standards," that is, they were not legal standards, but were used by the officials engaged in enforcing food laws as a guide in determining what products were probably satisfactory and what
23 were likely to be adulterated or misbranded.

Q. What was the effect of the advisory standards promulgated prior to the enactment of the Federal Food, Drug, and Cosmetic Act?

A. Although these, as I have explained, were not legal standards they were used by Federal and State Officials in their enforcement work and in general came to be well observed by food manufacturers and processors.

Q. Now tell us what changes in standard making procedure resulted under the new law?

A. The Food, Drug, and Cosmetic Act grants authority to the Secretary of Agriculture, later transferred to the Federal Security Administrator, to establish reasonable definitions and standards of identity, standards of quality and fill of container for most foods. It outlines a procedure to be followed. This procedure has been further amplified by regulations issued by the Secretary of Agriculture. There is no provision made in the law for a Food Standards Committee. The Food and Drug Administration, however, has continued to use such a committee in an advisory way.

Q. Has there been food standards making by the several States?

A. Yes.

Q. What influence has this had?

A. Most of the State standards have followed the
24 advisory standards issued by the Secretary of Agriculture. However, many standards have been adopted by States where no Federal standard has been in existence. This has demonstrated the desirability of some uniform system of standard making, since there are many instances where different standards exist in different States.

Q. Will you give a brief outline of Federal standard making for flour and the other related products included in the proposals upon which these hearings are being held?

A. Of these products now under consideration, there have been Federal standards, that is, advisory standards for the most part, in the past, for flour, Graham flour, whole wheat flour, semolina and farina. No Federal standards have been previously promulgated for durum

flour, cracked wheat, crushed wheat, whole durum wheat flour, self-rising flour and phosphated flour.

The first Federal standard for flour was promulgated by the Secretary of Agriculture in December, 1904, and published in Circular 13 of the Department of Agriculture. The standard was based on recommendations of the Food Standards Committee of the Asssociation of Official Agricultural Chemists. Such standard read:

"Flour is the fine, sound product made by bolting wheat meal and contains not more than thirteen and one-half
25 (13.5 per cent of moisture, not less than one and twenty-five hundredths (1.25) per cent of nitrogen, not more than one (1.0) per cent of ash, and not more than fifty hundredths (0.50) per cent of fiber."

According to information issued at the time it was intended by such a standard to include all flours of good grade and to exclude low grade flours. This definition was reissued in Circular 19 of the Department which was issued in June, 1906, and contained all food standards promulgated by the Department of Agriculture up to that time. The only change was addition of the word "clean" after "fine," making it read "flour is the fine, clean, sound product."

After the creation of the Joint Committee on Definitions and Standards this committee studied the question of further standards for flour. Many people at that time believed that standards should be formulated for various grades of flour and for flours made from different types of wheat. The committee devoted considerable study to this problem and held a hearing on proposals to formulate standards for patent flour, straight flour and clear flour from hard and soft and blended wheats. A great deal of opposition developed from the milling industry and no action was taken on the proposals.

Some years later the question of the reasonableness
26 of the limit for moisture in the standard for flour, was raised, due to changes in methods for the determination of moisture by the Association of Official Agricultural Chemists. As a result the standard for flour was amended in July, 1926 (F. I. D. 204), the amended standard reading as follows:

"Flour is the fine, clean, sound product made by bolting wheat meal. It contains not more than fifteen percent (15%) of moisture, not less than one and twenty-five hundredths per cent (1.25%) of nitrogen, not more than one

per cent (1%) of ash, and not more than one-half per cent (0.5%) of fiber."

A few years later the standard was further revised to lower the limit on nitrogen. This amended standard is the present advisory standard and reads as follows:

"Flour, Wheat Flour, White Flour. The fine-ground product obtained in the commercial milling of wheat, consisting essentially of the starch and gluten of the endosperm. It contains not more than 15 percent of moisture, not less than 1 percent of nitrogen, not more than 1 percent of ash, and not more than 0.5 percent of fiber."

None of the standards provided for bleaching flour. As a result of an agreement between the milling industry
27 and the Bureau of Chemistry it was agreed that bleached flour should be plainly and conspicuously labeled as "bleached." An announcement to this effect was made in December, 1920—known as Item 350 Service and Regulatory Announcement 26—December, 1920.

That completes flour.

Then Whole Wheat Flour.

The first standard for the product now known as whole wheat flour was contained in Circular 13, issued in 1904, under the name of graham flour. This definition read as follows:

"Graham flour is unbolted wheat meal.

"Whole Wheat Flour, Entire Wheat Flour, improperly so-called is fine wheat meal from which a part of the bran has been removed."

The definition for graham flour was included in Circular 19, issued in 1906, which included all standards issued up to that time, but definition of whole wheat flour was dropped.

In August, 1930, a revised definition was issued in Supplement 2, SRA, FD 2, Rev. 1. This standard had been recommended by the Joint Committee after studying the question and holding a hearing.

"Whole Wheat Flour, Entire Wheat Flour, Graham Flour, is the clean, sound product made by grinding
28 wheat, and contains, in their natural proportions, all of the constituents of the cleaned grain."

Mr. Goodrich: Right at that point, where you started quoting with "Whole Wheat Flour" and ended with "cleaned grain," that is a quotation of the standard itself?

The Witness: Yes. I was quoting that.

Mr. Goodrich: Go right ahead.

The Witness: The change there was that graham flour and whole wheat flour are recognized as the same product, whereas originally there had been a separate definition for graham flour and for whole wheat flour which originally was standardized as permitting some removal of the bran, but which the committee, or the Secretary at that time, said was improperly so called, and that only existed, that definition only existed for a short time.

Slight editorial changes were made a few years later and the present advisory standard reads as follows:

"Whole Wheat Flour, Entire Wheat Flour, Graham Flour. The product made by grinding wheat, and containing, in their natural proportions, all of the constituents of the cleaned grain."

Semolina and Farina:

Standards for these products were promulgated by the Secretary of Agriculture in August, 1928, in Supplement 2, SRA, FD 2. They were based on recommendations 29 of the Joint Committee on Definitions and Standards.

In order to be understandable they have to be considered in connection with standards for purified middlings. The three standards read as follows:

"Purified Middlings is the clean, sound granular product obtained in the commercial process of milling wheat, and is that portion of the endosperm retained on 10 XX silk bolting cloth. It contains no more flour than is consistent with good commercial practice, nor more than 16 per cent of moisture.

"Semolina is the purified middlings of durum wheat.

"Farina is the purified middlings of hard wheat other than durum."

These standards have been subjected to slight editorial changes and the present advisory standard reads as follows:

"Purified Middlings. The granular product obtained in the commercial process of milling wheat, and is that portion of the endosperm retained on 10 XX silk bolting cloth. It contains no more flour than is consistent with good commercial practice, not more than 15 percent of moisture.

"Seminola. The purified middlings of durum wheat.

30 "Farina. The purified middlings of hard wheat other than durum."

By Mr. Goodrich:

Q. Tell us of the origin of the proposals published in the Federal Register of August 3?

A. All of these proposals originated in the Food and Drug Administration. They were mainly based on recommendations of the Food Standards Committee. The Food and Drug Administration recommended to the Federal Security Administrator that they be announced for public hearings on his initiative. The Food Standards Committee first considered standards for flour, whole wheat flour, farina, and semolina. As additional information was developed, proposals for the various other products were added. Recommendations by the committee were based on information secured through the Food and Drug Administration and from recommendations and suggestions made directly to the committee by manufacturers and consumers.

Q. Do you feel that by reason of your connection with the formulation of the proposals you can give the reasons for their formulation?

A. Yes.

Q. Give these reasons as briefly as possible, please, sir.

A. In considering what foods should be scheduled
31 for standardization on the initiative of the Secretary—

Q. I believe that is the Federal Security Administrator.

A. They were originally given before the transfer.

The Food and Drug Administration basic foods for which advisory standards had already been in existence. In this category were flour, whole wheat flour, farina and semolina. In considering proposed standards for these products the need for standards for related products developed and proposed standards were formulated for durum flour, whole durum wheat flour, cracked wheat, crushed wheat, self-rising flour, and phosphated flour.

Q. Have field investigation been made for the purpose of obtaining information pertinent to the proposals involved in this proceeding?

A. Yes.

Q. Explain briefly the nature and extent of these investigations?

A. A series of investigations designed to secure information as to the methods of manufacture, labeling, and composition of products covered by these proposals were planned by me and carried out under my general super-

vision by representatives of the Food and Drug Administration. They included visits by field representa-
32 tives of the Administration to mills in various parts of the country where the various products under consideration were being manufactured. Firms manufacturing self-rising flour and phosphated flour by blending flours purchased from other mills and adding leavening ingredients or mono-calcium phosphate were included. Specimens of labeling of the different products manufactured were secured. Samples of flour were collected from the mills visited and where mill operators expressed opinions as to standards for the various products involved such comments were reported. In addition to samples collected from manufacturers samples of various products under consideration were also collected from consumers such as bakers, macaroni manufacturers, and so forth, and dealers in flours, and so forth. These samples were submitted by inspectors to various field laboratories of the Foods and Drug Administration and examined there. In many instances, subdivisions of the samples were forwarded to headquarters laboratories in Washington.

Q. Were written reports made of the progress and results of these investigations?

A. Yes, a written report covering the information secured from each of the firms visited was made by the inspector who made the investigation. These reports were forwarded to me and have been studied by me.
33 Specimens of labeling secured were submitted with reports. These specimens have been examined by me. Inspectors collecting samples made out a report known to us as a collection report and assigned a number to the report, and the same number to the sample. A copy of these collection reports was forwarded to me. After completion of analysis, the results, identified by the number given to the sample by the inspector, were also forwarded to me. I have studied these collection reports and the results of analyses and have had these results arranged in certain tables designed to group together products of similar character.

Q. Do you have these reports in the hearing room?

A. Yes.

Q. Are they in such condition that the persons attending the hearing may examine them during the course of the proceeding?

A. Yes. However, in the reports dealing with visits to various manufacturers, the name of the manufacturer has been deleted and any information furnished to the inspector as confidential has also been deleted.

Q. Now, why was that separated away from the rest of the report?

A. The information as to the identity of the firms visited has been deleted from the reports brought to
34 the hearing room although this information can be readily furnished if it becomes necessary. It was deleted because it has been the policy of the Food and Drug Administration not to introduce into the record names of manufacturers. Information given to inspectors as confidential has been delted in order to prevent such information being disseminated by way of these reports.

Q. Can you testify by way of summary with respect to the information contained in reports which are in the hearing room?

A. Yes. I am prepared to testify as to information contained in the reports dealing with visits to manufacturers, and so forth. I have had summaries of the results of analyses prepared and since these will have a bearing on the reasonableness of the proposals I believe such tabulated results should be made part of the record.

Mr. Goodrich: Now, if the presiding officer please, the reports referred to by Mr. Callaway are pretty large. They are contained in the boxes over back of the presiding officer's chair. To incorporate them as exhibits in the record would unnecessarily and unreasonably extend the record, and would serve no substantial benefit.

The results of the investigations have been worked up on a compilation of tables, and copies of those tables will be passed out in just a few minutes when they are
35 offered by the Government, but we do not propose at this time to put into the record the basic material which is in the form of inspectors' reports. If anyone cares to examine the reports, he can do so and Mr. Callaway can answer any question with respect to them, either by personal conversation, or you may ask him on cross-examination, anything with respect to those reports.

By Mr. Goodrich:

Q. Now, Mr. Callaway, did you select specimens of labeling of the different products here involved, also?

A. Yes. In general, specimens of labeling for each type of flour made by each of the mills visited were selected

and specimens of this labeling are in the hearing room for use in connection with the hearing if desired.

Q. I believe that you have those specimens of labeling in one of the boxes back of the hearing officer's chair, too?

A. Yes, they are bound together for purposes of keeping them from getting mixed up in flours of like kinds. We have both cloth labels and paper labels.

Q. Now, what did you include in the compilation of results taken from the inspectors' reports, and the analysts' reports on these collected samples?

A. The reports of collection made out by the in-
36 spector show where such samples were collected, the name of the manufacturer where such was available, the name of the dealer, and often information as to the use being made of the product sampled. Although this information may have some bearing on the consideration of results we have not wished to introduce names of manufacturers or dealers into the record and so I have simply designated in the tabulations the sample number assigned by the inspector. From the reports of collection which are in the hearing room the name of the manufacturer and dealer can be secured if so desired by the presiding officer.

For convenience the samples have been grouped into a number of tables. In each table there is another grouping of samples according to the State in which the product was manufactured. The date of collection of the sample is given. After each sample number and date of collection there follows a description of the designation given the product either by the manufacturer or the dealer. The analysis then follows. Altogether there are twenty tables which, for convenience, are designated as follows:

Table I Flour Said to Be Made From Soft Wheat;

Table II Clear & Low Grade Flours—Said to Be Made From Soft Wheats;

Table III Flours—Definite Information as to Wheat Used Not Furnished by Mill;

37 Table IV Clears & Low Grade Flours—Definite Information as to Wheat Used Not Furnished by Mill;

Table V Flours—Said to Be Made From Blended Wheats;

Table VI Clears & Low Grade Flours—Said to Be Made From Blended Wheats;

Table VII Flour—Said to Be Made From Hard Wheat;

Table VIII Clear & Low Grade Flours—Said to Be Made From Hard Wheat;
Table IX Phosphated Flour;
Table X Self-Rising Flour;
Table XI Flour—Labeled or Represented as Specially Prepared for Cakes;
Table XII Flour—Labeled or Represented as Specially Prepared for Pastry and Cakes;
Table XIII. Patent Durum Flour;
Table XIV Clear Durum Flour;
Table XV Miscellaneous Durum Flour;
Table XVI Whole Wheat Flour;
Table XVII Farina;
Table XVIII Semolina;
Table XIX Cracked & Crushed Wheat and Whole Wheat Flour;
Table XX Low Grade Flours.

38 These tabulations were made in my office under my supervision. Mimeographed copies have been prepared for convenience in order that such copies may be available to interested parties. The mimeographed copies will serve better than a consideration of original reports. Copies are available now for examination.

Mr. Goodrich: At this point I wish to offer the exhibit, as an exhibit, compilations referred to, and I have five copies here for the record.

In addition, we have approximately a hundred copies, and if you will allow a short recess I will pass them out to the people here in order that they may follow the testimony a little closer.

* * * * *

40 Is there any cross-examination of Mr. Callaway?

Mr. Gilbert: I don't know whether this question should come at this point or in connection with the specific proposal, but if it should come later, I will withdraw it now.

Mr. Callaway, do we have the period of time during which these field examinations were being made, or would that be completely covered by the Government's Exhibit No. 3?

Mr. Goodrich: The date of the collection is noted by each sample.

Mr. Gilbert: I assume that the Government was
41 also conferring with representatives of the Industry

during certain times, to ascertain what practices were existing at certain times?

Mr. Goodrich: Yes.

Mr. Gilbert: For the sake of the record, we would like that to be given, if possible.

Mr. Goodrich: I think it would come in better with respect to the evidence on the specific proposals.

Mr. Gilbert: Well, this question would come within the same class, then. Where we have no way of knowing how broad the coverage is on these compilations, as to the types of products and brands of the products on the market?

Mr. Callaway, have you any way of knowing how representative these examinations and investigations were of the Industry and the products of the Industry?

Mr. Callaway: Well, I can only express an opinion based on the extent to which different manufacturers were covered in connection with some of the other things.

You will come to that, I presume, in connection with the actual manufacturers of the flour. I believe there were about 75 mills covered, and the samples represented the products of those mills, and different parts of the country, as shown by the different states represented.

Later there were collection of some additional 42 samples.

Table 20 represents, largely, samples collected at random from different users of ordinary low-grade flours in different parts of the country, and in my opinion, for the number of samples it represents a fair cross-section of the different types of flour.

Cross-Examination by Mr. Gilbert.

Q. And you would think that this would be representative of flours that were on the market during a certain period of time, and the types that were being purchased and used by consumers during this period of time?

A. Reasonably so; yes.

Q. Just one other question. Maybe I had better ask it later.

When a representative of yours visited a particular plant, let us say that that plant was making all of the products covered by the proposal being today discussed, would examination and investigation be made with respect to all those products of the plant, or one, or a few?

A. Well, in this particular case, some of the original investigations did not cover all of the products, but as I explained originally, the flour, whole wheat flour, semolina and farina, were believed to be important enough to warrant standardization, as investigation developed on
43 inter-relating uses and the relative importance of various flours, other things were added. So in some cases subsequent investigations were made to cover products which had not been thoroughly covered at first.

In some cases, one mill or one manufacturer would make practically every product in the proposal. In a great many cases that would not be the case, but with respect to any particular manufacturer I could answer; but in general the answer would be that they were not all covered at the same time, even where the manufacturer made all of the products.

Q. Not all at the same time, but it may be that some one, or two, or three products of that manufacturer and in some of the others that he might be making, they are covered by this proposal; is that true?

A. That is possible; yes.

Presiding Officer Willcox: Are there any other questions?

Mr. Borries: I would like to ask a question.

By Mr. Borries:

Q. I notice here you show a mill from Mississippi. Is that a mill or a blender?

A. That is a blender. If it was put down as a mill, it should be a blender. There was no mill visited in Mississippi.

44 Q. I notice here that you have on Table 2 the clear flour at 38 A, and low-grade flour at 42 A. Is that the designation that the mill itself made?

A. These designations put down on the table, where they were collected from a mill, that was the designation given by the mill. Where they were collected from dealers, that was either a label designation or invoice designation, if there was one, or what the man said he bought it for, and those designations show that sometime the examination of the product indicates that the designation was probably not correct.

Presiding Officer Willcox: Excuse me a moment. Would you mind stating your name, for the record, and whom you represent.

Mr. Campbell: Herbert J. Campbell, Millers' National Federation. We have a problem we consider a very important one, and I don't know whether it best be brought out by this witness or perhaps by a statement of counsel for the Administration. It is a sort of mixed question of law and fact, and I might state it. I think the statement of it would clarify the proceedings to the extent of the
87 order and character of the proof that we put in. Perhaps this witness can say something about it and perhaps counsel can, and it is this:

Assuming that this definition and identity of flour in synonymous terms would become final, would there then be an exclusive appropriation of the term "flour" to the extent that would prohibit millers from marketing their products, in the intermediate flours, between this definition in Section 15 and the whole wheat flour?

For example, there are a great many flours that are in commercial use now, some of them for special purposes, but they fall within this definition, for example, in that except as to the granulation specification, they might be a little coarser ground, and they may be so that only 90 or 95 per cent would go through this 100 sieve.

Now, that is just an example. There are a great many other kinds of these intermediate flours. But our problem is whether or not we would be prevented from using the term "flour" with some qualifying adjective that would properly describe the product so as not to work an injury or a fraud upon the consumer. And I was wondering whether it would be a proper line of cross examination to develop from this witness whether their committee had had this matter under consideration and whether they had made any recommendation, or whether, aside from this
88 witness' testimony, whether the Department has any regulation, either in the process of formulation or already declared, covering that point, because it will materially affect us in our distribution of flour through the ordinary commercial channels if it should be the interpretation of this Department that because it has made a definition and standard of identity as to flour, plain flour and white flour, on the one hand, and whole wheat flour on the other, whether we would be prevented from using the term "flour" for these intermediate products which are fine products but don't cover or fall within some of the technical limitations of the definition of flour and, on the

other hand, in the milling process wouldn't be a milling of the whole wheat.

Presiding Officer Willcox: You understand, of course, do you not, it isn't within my jurisdiction to interpret the proposed regulation, or the effect of the regulation under the statute. Your evidence, I presume, would be directed to the desirability or not of this proposed regulation, and in so far as any facts you may want to bring out bear or lay a foundation for an argument you may want to make in a brief to the Administrator bearing on that question, I should suppose it is relevant.

Mr. Campbell: Yes; I want to make it very clear that we are not really in a sense—I mean, we are not trying to commit the Administration in advance on some proposition of the law, because after all the interpretation of the Act is a legal question. But I thought it would be very helpful if we could find out what the attitude of the Administration is on that question.

Presiding Officer Willcox: Have you anything to say to that, Mr. Goodrich?

Mr. Goodrich: I think the witness can testify with respect to what has been done, and aside from that he can't give any opinion on whether a certain thing would or would not be in violation of the Act. Of course, your question is in interpretation of Section 403 (g) of the Act and so far as that is concerned, it can't be answered at this time. We will just have to allow the product to be shipped and see if it is seized. Mr. Callaway can tell you, however, what the purpose of the Foods Standards Committee was on that, and their construction of that question in so far as it relates to the problem at hand.

Mr. Campbell: And right on that point, in that connection, there was another broad question that has been bothering us considerably, and perhaps this witness can bring it out. We have been proceeding up to this point or up until about a week ago on the theory that if we had a product that conformed all-square with Section 15, and added some additional ingredient that wasn't deleterious and harmful, and was a perfectly proper ingredient to add, and that if we conformed with Section 15 and put on our label what the ingredient was that was added, that we would be within our rights.

About a week ago we had an indication to the effect that if we added any additional optional ingredient to our flour,

that we would be violating the law, unless the definition and standard specifically set forth the optional ingredient that we use. I just want to make that point.

Cross-Examination by Mr. Campbell.

Q. Now, Mr. Callaway, in your deliberations in acquiring this data and then in your advisory capacity to the Food and Drug Department, was this problem considered by you as to what should be done either with respect to definition and standard of identity or what you think would happen to these intermediate flours that would fall somewhere between Section 15 and Section 15.020—Whole wheat flour?

A. Yes; that matter was discussed. I would say that the proposals were framed with the idea that nothing could be sold within the jurisdiction of the Act which was represented as or purported to be flour, white flour, plain flour or wheat flour, which didn't comply with the
91 proposed definition. The question of what would become of those things which did not meet that standard but which were legitimate products was discussed. It was the general idea, in the time that the committee was considering these, that such products, if they had a common or usual name of their own and were not confused with flour so that they could be sold without purporting to be flour, might be sold under the common or usual name.

If it is doubtful whether they could be handled in that way, then the people who made them should propose a definition for them, which would then put them in the class of a standardized food.

Q. But not with the name "flour" as part of that?

A. Not with the name "flour" unqualified.

Mr. Goodrich: Just on that point, if they propose a standard which includes the name "flour," such as, for example, bromated flour; then if they could sustain that, there wouldn't be any objection.

The Witness: That was the general idea, that if "bromated flour" is the common or usual name of the product, apart from "flour," and conceivably it might be sold under its common or usual name without purporting to be flour. If there was some doubt as to that, then by adopting a standard for bromated flour, it would make a

place for it under its own name as a standardized
92 food. That was the theory in general that was followed, or the theory in formulating the recommendations on which the actual proposals were based.

By Mr. Campbell:

Q. But that was the recommendation of your committee?

A. That was the recommendation.

Q. So that under your recommendation a miller would be prevented from the use of the term "flour" as part of the name, even when qualified by a proper descriptive adjective, unless it fell all-square within Section 15 or Section 15.020, Wheat Flour?

A. No, I didn't say that. When you qualify the word "flour," when that qualified word, qualified name, is already the common and usual name of a product well understood, the product might be sold under its common or usual name as an unstandardized food. If, however, there is any doubt as to whether there is a common or usual name of this product, then to relieve it of the danger of being said to be or purport to be flour, the safe way would be to propose a standard for it, under a name, and adopt a name and a standard for it.

Mr. Campbell: Will you just read that question of mine there.

(The last question was read by the reporter.)

By Mr. Campbell:

93 Q. What was your answer to it?

A. He might read it.

(The answer referred to was read by the reporter, as follows:

A. No, I didn't say that. When you qualify the word "flour," when that qualified word, qualified name, is already the common and usual name of a product well understood, the product might be sold under its common or usual name as an unstandardized food. If, however, there is any doubt as to whether there is a common or usual name of this product, then to relieve it of the danger of being said to be or purport to be flour, the safe way would be to propose a standard for it, under a name, and adopt a name and a standard for it.)

By Mr. Campbell:

Q. Isn't the first part of your answer rather negative, doesn't it rather negative the last part?—that is, that we would be prohibited from using the name "flour" as part

of the name but would have to adopt some name that didn't have "flour" as a part of it?

A. No; you could still have "flour."

Mr. Goodrich: Rather than have it debated on the record, we might have it argued orally.

The Witness: The part about which we do not seem to have a basis of common understanding is how far
94 the word "flour" might be a part of the name.

Mr. Campbell: That is right.

The Witness: For instance, if you call it "bromated flour," "flour" would still be a part of the name of the food. And if "bromated flour" is already the common or usual name of a food, then bromated flour might be sold under the name as an unstandardized food.

If, however, "bromated flour" isn't the common or usual name of that food, but it is known as flour, with sometimes the purchaser being told it contains bromate, then to make a place for that, the bromate would have to be recognized as an optional ingredient of flour or a separate standard adopted for bromated flour.

By Mr. Campbell:

Q. Did your committee in its deliberations give any consideration to the question of the necessity of including the definite name of the optional ingredients in the standard and definition of flour, or could optional ingredients be used under certain circumstances by a proper label description?

A. Well, there are two points involved in the considerations of the committee, one being whether an optional ingredient could be used. The question of the label statement of optional ingredient was as a rule not considered to any detail at all by the committee. That was consid-
95 ered to be more of a problem other than the standardization of the product. The committee was essentially concerned with whether the thing should be permitted as an optional ingredient. The technique of the label was given very little consideration.

Q. Was the recommendation of the committee with regard to the use of the optional ingredient unless definitely referred to in the standard?

A. Well, it was the committee's idea that optional ingredients could not be used in any product sold as purporting to be the standardized article unless it were recognized in the standard.

97 Mr. Gilbert: A. M. Gilbert, representing Hecker Products Corporation and Standard Milling Company.

Cross-Examination by Mr. Gilbert.

Q. Mr. Callaway, you were talking before with Mr. Campbell there about the exclusiveness that results from a standard in certain respects. I just wanted to ask you a question along that line, again bearing upon the fact that there is a certain exclusiveness that results from a standard. Before you were mentioning the possible labeling of a product for which there is a generally accepted name or for which there may be no generally accepted name,
98 and let us explore that one step further. This proposal as to flour would not permit you to use the name "flour" if it contained any ingredient whatsoever not listed in the proposal? Is that correct, sir?

A. You mean "flour," unqualified?

Q. Yes, sir, in the naming of the article.

A. I will have to say that what was the opinion in framing these proposals, that that was the opinion held by the committee in making their recommendations, that the name "flour" unqualified could not be applied to any article which was represented as or purported to be flour if it contained ingredients not recognized in the proposed standard.

Q. When you say "flour unqualified"—

A. I mean the word "flour."

Q. Yes. That would also cover a situation, or let us say I was going to add an ingredient I will call "X" for the moment, and we will call the product with "X" added. That, too, would be an unqualified use of the word "flour," so that we will understand the term we use. Is that correct, sir?

A. Mr. Presiding Officer, I don't wish to attempt to pose as an interpreter of the law, and I can't answer that without knowing the nature of the ingredient, and I don't know if it is proper.

99 If you mixed two standardized foods and said "flour with dried skimmed milk," and you wanted to sell it for something, that, to my mind, would make a product which did not purport to be flour and there would be no objection to it. But if you said "flour with—" and added something, some certain other common or ordinary food,

the mixture of which was recognized as a legitimate one, to my mind such a mixture, if not represented as flour, would not propose to be flour, would not purport to be flour, and there would be no objection to it.

But if you said, we will say, "flour with bromate," and the bromate were added in infinitesimal quantities, to the extent the person buying it would never recognize the bromate as being there and would not know what the bromate was, the bromate would be only a meaningless ingredient and the product would purport to be flour and it could not be done under the standard.

Q. Let us go one step further, then, and take another situation.

Presiding Officer Willcox: I assume these questions are really directed to what this witness can testify to in regard to the recommendations.

Mr. Gilbert: I trust it is.

Presiding Officer Willcox: His interpretation of the standard is one thing. His qualification to testify here
100 is primarily as a representative of the committee, in regard to this line of questions, I think.

Mr. Gilbert: Mr. Presiding Officer, in order to find out whether a proposed standard is reasonable, we at least have to understand its effect. And since the witness has testified in his opinion the proposed standard is reasonable, I think it is quite proper for us to ask him how that proposal would work out with a certain situation.

Presiding Officer Willcox: I am not making any objection to your questions, Mr. Gilbert, but I want to get clear what your question is addressed to.

By Mr. Gilbert:

Q. Let us go further, Mr. Callaway. I will be more specific on the ingredients. Let us suppose I am going to add to a flour a vitamine and let us suppose that vitamine is B-1. Very specifically, may I name my product "flour" and then say "with vitamin B-1 added," forgetting any problems under 403 (g) of the law?

Mr. Goodrich: We object to the question on the ground that it cannot be answered without 403 (g) interpretation and we do not have that interpretation. We can tell what the policy of the committee or the attitude of the Food Standards Committee was in framing the proposal, and that is all the witness can testify to. Any construction upon a given case of that kind would call for an interpreta-
101 tion of the law which he is not qualified to give. For that reason we object to the question.

Mr. Gilbert: I might say, before you decide on that, Mr. Presiding Officer, that it is because of 403 (g) and because of this proposal that it is difficult for at least some of us to find out the meaning, the exact meaning and effect of this proposal, and certainly if we don't know what is the meaning and effect, in certain sections, then certainly this record can't establish, so far as we are concerned, whether this is reasonable. We would like to know the meaning and then we would be in a position to know whether it is reasonable or whether we would have any objection to its reasonableness and would like to show its unreasonableness, that it is unreasonable. We think the objection of counsel is not properly taken in that regard.

Presiding Officer Willcox: As I said before, I don't think this witness should be cross-examined on the meaning of the regulation, of the statute. That is a question of law to be decided elsewhere. He has testified to his view or understanding of the intentions of the Food Standards Committee, and in respect to that you are certainly entitled to cross-examine him if you want to elicit further, if you want to elicit a further statement of the views as he understands them of that committee.

Mr. Gilbert: That is all I intend to find out, the in-
102 tention of that committee in making this proposal. This is what I am getting at. Was it the intention of that committee or whoever else framed this proposal, to permit the use of the word "flour" with such an optional ingredient as I mentioned, with a proper declaration of its presence?

Presiding Officer Willcox: Do you object to the question that way?

Mr. Goodrich: No objection. Go ahead.

Presiding Officer Willcox: Will you answer the question, please.

The Witness: It was the idea of the committee in framing the proposal to make, with respect to B-1 or other vitamins—sufficient evidence as to the use of these products was not available for them to provide for B-1 as an optional ingredient. It was their idea when a product like that was recognized as an optional ingredient, there should be a bottom limit set on it so that small amounts could not be used which would not be of any real value to the consumer but might be used only for advertising purposes and which would result in the opposite of promoting honesty and fair dealing.

There was no desire to prevent the use of any suitable optional ingredient, which evidence at this hearing would show was a desirable ingredient for flour. The question of whether the optional ingredient should be stated on
103 the label would depend upon the nature of the evidence. There would be two ways, in their opinion, of handling a product of that kind. The vitamin might be recognized as an optional ingredient or a standard might be proposed for some type of reinforced or vitaminized or some type of flour to which vitamins had been added. But it was their general theory that the question of what was suitable in the way of an optional ingredient was a question to be decided by the authority making the standard and not by the manufacturer who might wish to add anything and merely put on a labelled statement to that effect.

By Mr. Gilbert:

Q. Then to what extent—and perhaps the Presiding Officer as well as counsel can aid us on this—while this proposal here only sets forth certain optional ingredients and none others, the door is not closed for a proper showing for other optional ingredients?

The Presiding Officer: That is certainly true.

* * * * *

155 Appearances: (Filed September 10th, 1940.)

Mrs. Clara G. Snyder, 309 West Jackson Boulevard, Chicago, Illinois, appearing in behalf of Millers National Federation;

H. R. Goforth, 3859 Lyons View Road, Knoxville, Tennessee, appearing in behalf of J. Allen Smith & Company;

Ezra Levin, 155 N. Clark Street, Chicago, Illinois; appearing in behalf of the VioBin Corporation.

325 Proceedings.

Presiding Officer Willcox: The hearing will please come to order.

Whereupon W. H. STROWD was presented as a witness on behalf of the Industry and, being first duly sworn by the presiding officer, was examined and testified as follows:

Direct Examination.

By Mr. Campbell:

Q. Will you please state your name, residence and occupation?

A. W. H. Strowd, Secretary of the Soft Wheat Millers Association, Nashville, Tennessee.

Q. And what have been your foundation and qualifications along the lines of milling with respect to chemistry or any other factors?

A. Well, I was graduated from the University of North Carolina in Chemistry, and took advance work—

Q. In what year?

A. Do I have to give that—1909. And I took post graduate work at the University of Wisconsin and secured my Ph.D. degree there in 1920, in bio-chemistry. I took courses in animal and plant nutrition. And then, for 10 years

I was in regulatory work in the State of Wisconsin

326 and had charge of the enforcement of regulatory laws, rather similar in character to the old Food & Drugs Act, and I collaborated with the United States Food & Drug Administration in shipments relating to interstate shipments in and out of Wisconsin.

Q. What department of Wisconsin?

A. The Wisconsin Department of Agriculture. I was chief chemist and had charge of enforcement of laws relating to the sales of feeds and fertilizers, and so forth.

Q. How many years were you there?

A. In that position I was there 11 years. Also for 2 or 3 years I was chairman of the executive committee of the National Association of Feed Control Officials, the duties of which were largely to formulate definitions and standards on feed stuffs.

Q. Where was that?

A. That was an organization of State and Federal Feed Control Officials, with a meeting once a year in Washington. That was just an honorary position in connection with the work in Wisconsin, you see.

Then, in the last 15 years, I have been secretary of the Soft Wheat Millers Association, which is an organization to develop the uses of, and improve the quality of soft wheat flour. During part of my term as secretary of
327 that organization, we conducted laboratories in home economics and nutrition and in chemistry. I had general supervision of those, and we made certain investigations of those and published certain reports relating to the human nutrition, particularly with reference to the way flour fits into the diets.

For the past couple of years I have been devoting special attention to the desirability of the addition of minerals and vitamins to white flour in respect to the Public Welfare, and have studied the literature on the subject and interviewed many leading nutritionists in different parts of the country, and have made a number of different tests of our own and worked in collaboration with the Research Department of many corporations which had an indirect interest in it, as well as millers.

Q. And have you also made it your business to keep abreast of the literature on that subject during the past few years?

A. Yes, sir; I have tried to.

Q. Will you please state, in your own way, what optional ingredients you would recommend to be included in the definition and standard of flour as comprised in the title of Section 15, the caption 15.

A. You mean the addition of vitamins and minerals?

Q. Yes.

A. Well, I don't offer a complete list. I don't
328 say that there are no others. I want to say that first of all.

Q. Yes, I understand.

A. But we believe the following are warranted.

Q. My question was the ones you proposed. There will be other witnesses following you, perhaps, who will propose certain additional ones, too.

A. I just wanted to make clear my recommendation or my list is not complete.

Vitamin B_1 or thiamin chloride; Vitamin B_2 or riboflavin, sometimes called Vitamin G; nicotinic acid, also know as

an anti-pellagra factor; iron compounds and calcium compounds.

Q. How about processed wheat germ?

A. Well, processed wheat germ is a product we believe is justified in being added here—not strictly speaking of a vitamin or a mineral.

Q. If you will take these up in whatever order you perfer to discuss them.

A. Yes. I will first define the terms commonly employed in the addition of vitamins and inorganic compounds, and I will use them subsequently in this discussion, as I will use them, for the sake of simplicity:

Inorganic elements and compounds needed in nutrition are called minerals.

329 These are colloquialisms to a certain extent.

"Restoration" means the returning to a processed food the vitamins and the minerals in amounts removed from the raw material in processing.

"Fortification" is adding to a processed or natural food vitamins or minerals in excess of that found in the natural food.

I will now make certain observations and citations relating to restoration and fortification, based on the knowledge of nutrition, which will be supported by a brief to be filed later.

I wish to say, first, that complete diets are available to the consuming public consisting only of what are called natural foods or consisting of combinations of natural and processed foods in which there are no additions of vitamins or minerals to either food class.

That is to say, I take no issue with anyone who states that fortification is not necessary under ideal conditions, but that neither of the above-named types of diets is universally consumed, is demonstrated by the widespread prevalence of deficiency diseases, and which are known among all income groups.

For instance, Dr. Russel Wilder, of the Mayo Clinic, in an address made last spring or summer, a year ago, which is reported in the North-Western Miller for July
330 5, 1939, pointed out that we see in our hospitals, coming into our hospitals daily, persons suffering from beriberi, disguised as a number of diseases, which he enumerated.

Dr. George Cowgill, of Yale, called attention to the same effect in an article appearing in the Journal of the Ameri-

can Medical Association for December 9, 1939, in which he put up a strong case for the addition of Vitamin B_1 to staple American foods.

So we are confronted with a condition and not a theory, and on that basis, and based on the opinion of many of the outstanding nutritionists in the country, we believe it is the place for the addition of vitamins and minerals to white flour in the interest of public health.

Nutritional deficiency diseases are probably most prevalent among low income groups. Certainly there are more dietary essentials lacking in the diets of the poorer classes, the low income groups, than in the case of the middle and upper income groups. This is shown in a very striking way in Circular 507 of the United States Department of Agriculture, which is the result of a survey of city workers, and grouped according to income. It was shown in the cases of the lower income groups that they not only were suffering from lack of vitamins and minerals, but, in many cases, an analysis of their diet showed they were suffering from lack of proteins and even lack of caloric intake.

331 We believe fortification is desirable, but we want to stress the fact that it would have its limitations in dealing with those groups.

Among the higher income groups, diets in general were far more efficient and were inclined to be better balanced but we do know there are a large number of people, due to individual tastes or probably irregular metabolism, growing children with a sweet tooth, and things of that sort, not getting proper diet, and the limitation is entirely independent of income.

The improvement of public health by better balanced diets should, and must lie, in part, in dietary changes in food habits by the slow process of education: but taste and custom, as well as problems of manufacture, food preservation, transportation, economy and even to some extent health, make the continued use of processed foods inevitable and desirable.

A broad program of restoration and fortification of natural and processed foods will, in the opinion of many authorities, improve the health of the public.

I would like to make one comment, or take a paragraph from a paper read by Dr. Lydia Roberts, head of the Home Economics Department of the University of Chicago, delivered before the Society of Nutritions, at Toronto, last

spring, a year ago, which I believe is a fair and reason-
332 able and conservative statement of a policy with ref-
erence to fortification of foods. This is published in
the Millbank Memorial Fund Quarterly for July, 1939:

"To sum up, I believe that, if it could be properly safe-guarded, a judicious use of fortification might be of decided benefit in a general program for better nutrition. If undertaken, leadership in the movement should be given by physicians and specialists in nutrition who should work out carefully considered policies as to the foods which should be fortified, the materials to be added, and the absolute and relative amounts to be used, and who should also direct the distribution and promulgation of the fortified products."

In general, I think that sums up pretty well my view. In other words, fortification should take place under strict regulations. As far as I am personally concerned, my interest in this would have remained academic had it not been for the understanding that under this new Food & Drug Act there would be strict regulations to safeguard the interests of the consumer, as well as to protect the honest producer against dishonest competition.

Therefore I believe that this is one time that regulation is desirable. Of course, the regulation should be practical
and should not be lost in a maze of technicality.
333 and we should be actuated by the desire to protect
the public and by the desire not to throw up any im-
practical restrictions around the manufacture, to make your label so complicated that the consumer will become lost in a maze of print and technicality.

But I believe it is possible to do these things in a practical way, and I think, above all, in the allowance for optional ingredients to be used in connection with flour, that there should be a machinery set up for the very quick and simple and easy introduction of new optional ingredients to be added as the rapid progress in our knowledge of nutrition might justify.

Q. Should there, in your judgment, be both a roof and a floor to the amount of these ingredients?

A. There certainly should be a floor and there should be a roof in some particulars. I think that the economic roof will be ample to keep out the weather and some others, and there is no way, as far as we know—ours, for instance, happening to be one which is quite expensive—and, as far as we know, excessive quantities do not hurt, as well

as costing $700 a pound as against flour costing 2 or 3 cents a pound, I don't think there is much danger of their putting too much in it.

Q. What I had reference to in speaking of a floor was in fact that this whole proceeding, as I understand it, is predicated upon establishing relations that will promote honesty and fair dealing in the interest of the consumer, and you would want to guard against, would you not, certain manufacturers purporting to sell a product containing these ingredients where they only put an infinitesimal amount in it?

A. My answer to that was unqualified; yes, Mr. Campbell. I was discussing whether or not the ceiling was necessary, and I would say probably the ceiling would be desirable, but the floor, absolutely yes. And I think it is highly desirable to have a uniform method of labeling. For instance, suppose one man comes out in the interest of the consumer and endeavors to tell how much of a certain dosage of it, or a certain per capita use contains so much in vitamins or minerals, so that whatever the per capita use in this country happens to be, if labeled the same one fellow might have 2½ times as much as the other.

So it is important that the roof cover that. I hope that is contemplated.

Q. Yes.

A. We hear a lot about natural foods and some people make a sort of a fetish of it, even to the point where they won't eat food whether it is good for them or not, or whether they like it or not. Sometimes I think this is a throwback to the old fetish of the Pilgrims, or something, and somewhat from the idea that it is wrong to enjoy good food. However, the only natural food designed for human nutrition is mother's milk. Wheat contains certain vitamins and elements placed there by nature for the perpetuation of the species, for the wheat plant, and God Almighty happened to have put it where man could get it, but He didn't specifically try to balance it for man's welfare.

Nevertheless, we must admit that our knowledge of nutrition is incomplete, and in the absence of better information, as imperfect as it is, fortification and restoration of the amount of dietary essentials removed, being restored in the quantity in the original wheat grain, is a pretty good, broad, general rule.

However, when available information should indicate

rather definitely that full restoration should be substituted for in whole or in part by partial restoration or fortification, we should not follow that rule.

Now, then, I will go into a little detail on that on the way we have tried to work that out. I want to ask for the addition as optional ingredients of those mentioned in your first question, and I want to discuss Vitamin B_1, nicotinic acid, and calcium compounds to some extent, because they are the ones which the mills with which I am
336 associated are using in their fortifications. The others will be discussed by witnesses who have had more experience with them than I have had, that is, the Vitamin B_2 and the iron compounds.

I understood yesterday afternoon—and if I am wrong, I would be glad to be corrected—that you want some discussion as to the amounts that should be added, details of the ceiling and the floor. I thought that was coming up in the hearing. I had previously thought that was going to be discussed in the hearing, on special dietary foods, but I find yesterday I was supposed to say something about that.

Is that correct, Mr. Callaway?

Well, let us first consider Vitamin B_1, or thiamin chloride. That probably shares with calcium the elements that are most likely to be lacking in American diets, and the most important are those two. As you all know, of course, recently the British Parliament has passed a ruling that all flour must contain Vitamin B_1 and calcium.

Now, as to the quantity of B_1 desired, I hardly feel in a position to offer either a floor or a ceiling. I can, however, tell the amount that we are adding and the basis therefor, and this quantity was decided upon after consulting with some of the leading nutritionists of the country.

There seems to be a tendency, a proper one, or
337 rather, a movement, probably inspired by a pending regulation, to state the vitamins and minerals present in foods for which special dietary claims are made, in quantities that are recommended by the manufacturer in which they should be used. For instance, they put—and I don't know much about baby foods—but I suppose, say, you advocate the intake of 4 tablespoons a day, you are supposed to tell how many unit of B_1 or grams of calcium that would contain.

Of course, in flour we don't recommend any dosage, but we have tried to follow the spirit of that movement which we think is a wholesome one, and have therefore made our

declarations on the basis of the average per capita consumption of flour per day.

We got into this—and when I say we I refer to some 22 mills, working on a more or less uniform formula and perhaps I should not say "more or less" but working under a more or less uniform formula I have developed, that policy of stating on the label the quantities which seems to be followed by the British Government. I believe they are reporting how much Vitamin B_1 and calcium should be added per day, based upon the per capita daily consumption.

I don't know whether the flour will be labeled that way or not, but that is a rule to be universally applicable.

338 There is some difference of opinion as to the quantity of B_1 required per day for an individual. Of course, there is a difference in different ages, and for people of different ages there is a difference in individuals, and some people may have some mild sickness such as diarrhea, as Dr. Cowgill pointed out, but I think the Government has set up a minimum of 250 international units per day—Is that correct, Dr. Nelson—not especially as a recommendation but as a guide as a general minimum.

Q. 250?

A. International units of B_1 per day.

We have examined some diets and gone over a good many typical diets from the standpoint of B_1 content that were B_1 deficits, in diet, and we have found none that didn't contain at least half the B_1 content required, and you can make allowances for the individual tastes, and so forth.

Another thing I want to point out, too, is that at the present time the average intake of calories in the United States is approximately one-half from flour and sugar combined. So we are adding 150 units of B_1 to $6\frac{1}{2}$ ounces of flour. That is, we are declaring that on the label. We are actually adding enough more than that so that we will always be right, on the theory they will furnish a little more than half the requirement of B_1 based on the per capita intake.

339 We are also supplying as many units of B_1 in proportion to an individual's requirements as flour plus sugar supplies in calories.

I might also quote from the article by Dr. Cowgill, referred to a while ago in which he urges the fortification of staple foods with B_1 and particularly flour, as follows—and this is the article from the Journal of the American

Medical Association, Volume 113, December 9, 1939, by Dr. George Cowgill. He says:

"Elsewhere there has been pointed out that the need of adults seems to be not less than about 10 international units of the vitamin per 100 calories; children apparently require amounts ranging from 20 to 25 international units of the vitamin per 100 calories. The wisdom of adding the vitamin to foods in such amounts as to give at least 25 international units per 100 calories would seem to be unquestioned, because this would bring the products up to the irreducible minimum for a child and making it a little better than that needed by an adult."

That also is approximately the quantity we are adding to flour in B_1. So I am just—

Q. Right there, Doctor. When you say "We are adding" did these mills you mentioned, I believe some 23 in number—

A. Yes.

340 Q. —are they now manufacturing and selling flour with Vitamin B_1 added to it?

A. Yes.

Q. Could you tell for the record—

A. They are offering it for sale, I will say, at least. That would be technically correct, since I am under oath.

Q. I was wondering if you would care to discuss this as to something with respect to the volume.

A. No, sir; I wouldn't, except that I will say this, that it has been on the market only three or four months. We are more or less feeling our way along and the volume is not large. However, we have a considerable investment in it in the way of research and preparation and bags and materials, and so forth.

Q. But it has been sold? It isn't just theory?

A. Yes, sir; it has been sold. But to say it is any substantial proportion of the flour in the United States, it is not, but it has been offered for sale in at least sixty towns and cities that I know—and I haven't a complete list—by these 23 mills, and some of it has been sold, and it has been given repeat orders, for that matter. But, as I say, it isn't anything to brag about.

Q. I am sorry I interrupted you.

A. That is all right.

341 I think that covers the basis of the quantity of B_1, and, as I say, I don't offer that either as a floor or a ceiling. I am merely telling you what we have arrived at

and why we have arrived at it, and why we are adding that quantity.

There is also the question, which is rather an important, and certainly a pertinent one, as to the stability of B_1 in flour, up to the time that it is consumed. B_1 is a thiamin chloride—and, of course, those terms are synonymous—and quite stable in the presence of acids, and is quite unstable in the presence of alkalis when heated moderately. It has been investigated; there has been some investigation, at least on the loss of B_1 during cooking in various products. I refer you to an article appearing in the Journal of Nutrition for March, 1940, at page 285, entitled "Effect of Cooking Upon the Thiamin Content of Foods" by Miss Aughey and Esther Peterson Daniel. They have gone rather extensively into the loss of foods, well, particularly vegetables and meats. They point out that the thiamin losses vary from a very small percentage up to, say, 43 per cent loss of roast pork loin. And they find that in the presence of a small amount of sodium bicarbonate, the destruction of thiamin was markedly increased in green peas and snap beans, but had no significant effect upon the thiamin content of boiled navy beans.

342 Q. Is "thiamin" a term that is used synonymously with thiamin chloride?

A. Thiamin and thiamin chloride and Vitamin B_1 are practically all synonymous. I mean, you will find them all appearing.

I point that out with reference to that effect of sodium bicarbonate because, of course, sodium bicarbonate is used in baking. Our mills are offering our flour containing thiamin almost entirely to the same place which is largely baked as a chemically leavened product in counter-distinction to the yeast product, and, of course, in the chemical leavening, bicarbonate of soda is the ingredient, is an alkaline ingredient as referred to there. So if you would have an excess of alkali, it might be destructive and that is properly a question that should be studied pretty carefully with respect to the stability of the thiamin chloride in the baked biscuits and breads and so forth, the chemically leavened baked products.

There are some baking powders that lean rather to the alkaline side. You can bake a biscuit with certain baking powders and the reaction of the dough crumb will be about 7½, will produce a p. h. of 7½. Well, we have some in-

formation that a p. h. of 7½ causes a loss of around
343 50 per cent in the thiamin chloride during the baking process.

Q. What does the "p. h." mean?

A. That is the hydrogen iron concentration and relates to the acidity. I was assuming I was talking to technical men. I am glad to stand corrected, though. At any rate—

Q. I didn't mean to divert you.

A. That is all right.

The neutrality point is 7. That means that it is neither an excess of acid or an excess of alkali, but the higher up it goes, the more it goes toward alkalinity. If you get a biscuit, in the baking of biscuits, and so forth, through an excess of alkali up around 7.5, the biscuit will begin to assume a yellow tinge, and if it gets up much above that, it is both horrible looking and horrible tasting. So you want to be very careful not to get an excess of alkali.

So that, in itself, will form some break on the alkaline reaction of the crumb during baking that will result in the loss of thiamin.

We are adding to the thiamin to our flour enough acid salts which serve the treble purpose of regulation of p. h., of leavening, of neutralization, a source of calcium, in such a way that the reaction of the biscuit will be
344 down to around 7 to 7.2 where the loss is very small.

Tests show that at 7.2 the loss in baking is approximately 15 to 20 per cent. Incidentally, we put 15 to 20 per cent more thiamin in the flour than we declare. At least, there is that much more there including the flour content plus the added amount. And I believe that is pretty close to what it is with baking bread, according to this article, which cases about 15 per cent loss. So that will bring us to about the same thing as baking yeast bread. We are adding this to what we call the self-rising flour. We are going to request the same vitamin and mineral addition to the self-rising flour in the definition, but I might also say that to fortify what we may call the non-self-rising flour, we add these salts also and it carries an excess in there so that if we get baking powders on the alkaline side as much as they normally go on that side, it will bring the p. h., the hydrogen iron concentration to a point where the loss is not great.

There is also a pertinent question as to the possible loss on bleaching, flour bleaching. Of course, in the bleaching of flour, you use small amounts of very powerful oxidizing

agents, but they are used in very small quantity, and, generally speaking, thiamin chloride is quite resistant to oxidization except in alkaline solutions which would
345 not be the case in the flour. But we have actually tested that out in the case of the two strongest bleaches.

Dr. Frey, Director of Research for Fleischmann, has found that there is practically no difference between the thiamin content of bleached and unbleached flour. That is, the contents. That refers to the natural thiamin chloride content of the flour and not added content. The action of the chlorine bleach and the nitrogen trichloride bleach is practically instantaneous and we don't add the thiamin chloride until after it has come from the mill, usually. We put it into a batch mixer and mix it, so that would not affect neither the nitrogen trichloride bleach or the chlorine bleach would affect the added thiamin chloride because it is already spent before we add it.

However, there is another bleach widely used, as you know, the benzoyl peroxide bleach, diluted, and that bleach is added to the flour either on the stream or afterwards, and it takes about 48 hours to complete its action. So, naturally, since we may mix pretty soon after the flour is made, the thiamin chloride goes into the flour before the benzoyl peroxide has completed its oxidation process. But we have made careful studies on that in which we have mixed thiamin chloride and the diluted benzoyl peroxide, that is, the benzoyl peroxide with the filler, the
346 commercial product used in flour mills at the same time, and over a period, we have found absolutely no loss, that is, no difference in the vitamin content with and without the addition of benzoyl peroxide.

As to nicotinic acid, first of all, that is a product that is rather rich; it is a constituent in which wheat is quite rich; wheat grains are one of the richest sources of it; it is an anti-pellagra factor. Our knowledge of it is not very extensive. Probably the best authority in the United States on this subject is Dr. Elvehjem, who first identified nicotinic acid as the anti-pellagra factor. He presents this view on it, that to what extent the nicotinic acid is deficient in the American diets, he cannot say definitely. We do know that there are some cases of pellagra which are cured by nicotinic acid, but he says it must be remembered that beriberi was known in the Orient for many years and was considered the standard B_1 deficiency disease before

it was recognized that diseases with very different symptoms are also a certain type of beriberi. He says we may find the same thing with respect to nicotinic acid.

Now, he said as long as you remove an essential vitamin and nutrition in the milling of flour, "I believe it is the part of good judgment to return that nicotinic acid in quantities not exceeding that found in the wheat
347 grain," and on that basis we are adding nicotinic acid.

As to its stability, the literature is not very extensive, but in what there is, there seems to be a pretty general opinion that it is a fairly stable compound, and we don't seem to have to worry about it. That is the opinion of Dr. Elvehjem.

Now, the calcium compounds, we are using two forms of calcium, the monocalcium and dicalcium phosphate, and the value of these substances in nutrition is established and well-recognized.

Of course, you know we add these vitamins in very small quantities, and it is necessary to have a carrier. After considerable study we finally decided, for a carrier, on a wheat product, a wheat germ which has been partly dried and de-fatted. The moisture has been reduced from around 12 to 5 per cent, and the fat reduced from approximately 12 down to 1.

It is a very stable compound. We have kept it in a paper bag in the laboratory away from the mice for about a year and it is still sweet and sound. And we find it rather uniform in character so we use that primarily as a carrier for the vitamins. It has been studied and approved by competent authorities as to uniformity, and so forth.

So far as the Vitamin B_1 content is concerned, we
348 don't lay much stress on that. It is very small, but it does make a very nice carrier for the nicotinic acid and the Vitamin B_1. We add that to the germ and make it convenient, you know, for the miller to add an easily measurable and admissible quantity to his flour in his batch mixer, where it is mixed the same way self-rising flour is mixed.

I believe that about covers what I had to offer, Mr. Campbell.

Q. I wanted to get this straight about this de-fatted and de-hydrated wheat germ. Is that sometimes called a processed wheat germ?

A. Yes; it could be easily described as that. That is

just what it is. I don't know whether it is called that or not, but that is what it is.

Mr. Goodrich: That carrier is the processed wheat germ, you say?

The Witness: Yes.

By Mr. Campbell:

Q. You spoke of these optional ingredients in general, and then you took them up seriatim but I perhaps—

A. Pardon me; I say in respect to that, Mr. Campbell, or tried to say that Vitamin B_2, or riboflavin, and iron compounds will be discussed by other witnesses. We are not using them. We are favorable to them, but I think
349 other witnesses who will testify later will discuss them in detail as I have, with respect to B_1 and calcium and nicotinic acid, the others who have more information on the subject than I have.

Q. But as to these, you described ~~specifically~~—

A. Yes.

Q. That is, calcium compounds, thiamin chloride, nicotinic acid, and processed wheat germ, are your group of millers using all of them at the present time in some volume?

A. That is right.

Q. So that they are beyond the theoretical stage? They have actually been added to the flour and sold in commercial channels?

A. That is right.

Q. And you are recommending that they be introduced as optional ingredients under the definition and standard of flour, white flour, wheat flour, and plain flour? Is that correct?

A. That is correct.

I might say, further, that I am also advocating the addition of the others. I am in sympathy with it for various reasons.

Q. Your presentation on that will be completed by subsequent witnesses?

350 A. That is right. I am merely saying I approve of it.

Q. Are you asking that these optional ingredients also be included in any of the other definitions and standards proposed by the Food & Drug Administration?

Mr. Goodrich: We object to including that in at this point; it will confuse the record.

Mr. Campbell: It is all right. He can cut it out.

Mr. Goodrich: I believe you said you used it in self-rising flour?

The Witness: In self-rising flour, and phosphated.

Mr. Campbell: Off the record.

(Discussion off the record.)

That is all I have on direct.

Mr. Goodrich: I move that we take a short recess before the cross-examination begins.

Presiding Officer Willcox: We will recess for five minutes.

(Brief recess.)

Are you ready to proceed?

Mr. Goodrich: Yes, sir.

Cross-Examination by Mr. Goodrich.

351 Q. Doctor, on the addition of Vitamin B_1 to plain flour, you advocate generally that it be added to restore the flour up to the whole wheat level, or fortification generally?

A. Well, I didn't exactly advocate that, sir. I advocate 150 international units—

Q. Yes, sir.

A. —to 6½ ounces.

Q. Wouldn't that be about the same as whole wheat?

A. Well, when you talk about whole wheat, you get into a lot of variations. For instance, you take in Bulletin 707.

Q. What bulletin is that?

A. Technical bulletin 707, of the Department of Agriculture. They show the B_1 content for soft wheat at about 120, of hard wheat I think at around 155 international units per 100 grams, and spring wheat around 175. That is from memory, but that is roughly what it is.

Our products would be probably in the neighborhood, I would say, around 80 per cent of the figure for soft wheat. On the other hand, if you would analyze a lot of soft wheats, you might find some down as low as we are. We have gone along on what we think the individual requires to supplement the American diet, rather than try to reproduce what is in the wheat grain. I think we have 352 more evidence on the B_1 than they have on the other things. For instance, on nicotinic acid, we have tried to stay within the limit—

Q. Yes, I understood your testimony on that.

A. Yes, sir.

Q. This thiamin chloride which you add is a symthetic product, is it not?

A. Yes, sir.

Q. Have you made any experimentation; has any experimentation been conducted with soft wheat in milling back in the wheat certain of the mill streams which are high in Vitamin B_1, producing the Vitamin B_1 desired in that way?

A. Well, I wouldn't say any experimentation has been made along that line. Our idea, I might say, in developing this is that after we have reasonably assured ourselves of the stability and the value and so forth of it, that the tremendous job, the really big job, is getting consumer acceptance. If you introduce those high milling streams, I mean, those milling streams that have a high B_1 content, while they are wholesome, and so forth, you are detracting from the palatability of the product. So there is a cardinal rule in our formula to use only a high grade flour, which, incidentally, is of low B_1 content; and we haven't studied additions of flour streams of high B_1 content; we must consider it from the standpoint of palata-
353 bility, as the ones putting out advertising on it. We are ready to offer, however, flours of other kinds, on low prices, the cheaper grades of flour; but primarily we are trying to build up our demand and get consumer acceptance on the good quality flour, and for that reason are not bothering about the low streams, because we think it will detract from it, from the taste standpoint—and people will go for what they like, regardless of whether it is good for them, unless they are sick, or something like that.

Q. Your product probably sells, then, for an amount substantially higher than is received for plain flour?

A. Yes, sir.

Q. About how much more is it?

A. Well, do you think that is really pertinent to this discussion, to get into the question of price? If we take the lower grades of flour, the cost is not very great, and when you get into the higher grades, it is somewhat larger. We are not putting out, necessarily, that same identical grade, in some cases; and it just doesn't seem to me that that has any bearing on the subject.

Q. You object to the question?

A. Well,—

Q. O. K.

A. That is the gist of it.

Q. Yes, sir.

A. I hope you won't insist. I don't mind whispering it to you, but I don't want to tell all my competitors my secrets.

Q. Why is this flour with a certain stream less desirable? Is it because of the higher ash content?

A. No, ash is merely an indicator that happens to be constant.

Q. Is it a measure of the degree of separation?

A. I would say it is more a question of quality of gluten; the lower the gluten quality in a mill stream, the higher the ash. That is more or less a coincidence. Of course, one thing, you get more bran particles from the low grade stream than from the heart of the wheat where the best quality of gluten is.

Q. How much ash does the addition of the processed wheat germ as a carrier for your thiamin chloride add to the flour? Can you tell us that?

A. Oh, I would say probably .02 or .03, but that doesn't affect the quality of the flour.

Q. I understand, but some allowance will have to be made for the addition of that?

A. As far as that is concerned, the addition of the
355 calcium phosphate is what would really make a difference in the ash. But that assumes the status of phosphated flour and self-rising flour.

Q. Yes. I want to get on this processed wheat germ now. Does it have any effect on the ash?

A. Not enough to worry about. Not to make any considerable difference as to affecting your old standards or the one you have under consideration, or the Milling Industry's substitute. That would be insignificant.

Q. Yes, sir. Thank you.

You would advocate no change because of this?

A. No; of course, I want you to recognize—

Q. Yes, I understand your other position; yes.

Doctor, wheat germ is recognized as one source of Vitamin B_1, isn't it?

A. Yes.

Q. Is there any substantial amount of Vitamin B_1 in the processed wheat germ which you use as a carrier?

A. Well, you see, the wheat germ will contain about, on an average, while usually called 10, nearer 8—

Q. International units?

A. Per gram, I should say, 10 international units per gram; yes. And this processed wheat germ contains all of the B_1 of the original, none of it is lost in the
356 process, and then by removing about 20 per cent in oil and water, it is really increased about 25 per cent, you see. So a wheat germ contains 8 international units per gram, and you take out this oil and water and probably increase it to 10. However, in order to bring up the wheat germ and in order to bring up the Vitamin B_1 content of the wheat germ alone to the level which we are trying to raise it would require so much that it would render it unsuitable from the baking standpoint, you understand. It would take about 8 per cent of the wheat germ to bring it up to this B_1 content unless fortified with synthetic vitamins. A small amount of it will, I think, improve it to some extent. That is, the approximate mill run.

Q. Your addition of synthetic Vitamin B_1 would have no effect on the vitamin B_1 content of the processed wheat germ carrier?

A. Pardon me; I didn't understand that question.

Q. Your addition of thiamin chloride would be in addition to the amount of Vitamin B_1 you added incidentally with your carrier?

A. That is right; yes.

Q. When you testified with respect to an article appearing in the North-Western Miller for July 5, 1939, to the effect that many persons are suffering from beriberi, beriberi is a disease combatted by Vitamin B_1, is it not,
357 or prevented by that?

A. Yes, sir. That is the disease that has been known in the Orient for many years. More people died from beriberi in the Japanese Navy back about the last part of the Twentieth Century than were killed in the Russo-Japanese War. At that time it was thought to be an infectious disease but it was learned it could be cured by diet. I will quote this statement put in quotation marks, from Dr. Russell Wilder, who, I understand, will be here and discuss this subject;

"The result has been (referring to the American Dietary) that in our hospitals we see beriberi almost daily masquerading as polyneuritis, retrobulbar neuritis, toxic psychosis, toxemia of pregnancy and in other disguise."

Q. Are we to conclude from that, do you think, that that is a prevalent disease, or a diet deficiency?

A. I think probably you know and I know of a good many cases personally. There was a man in this room who told me how much he was helped by B_1. My own brother was unable to walk, for example, and they carried him over in an ambulance to the Duke University and they put him on B_1, and a week later, he was walking around with a cane. Thirty days later he was playing golf. We don't offer this flour as a therapeutic.

Q. Yes, sir. I understand.

358 A. A prophylactic probably isn't a good word. We want to offer it as a part of a balanced diet so that people won't get that way.

Q. Going back to the addition of Vitamin B_1 with your method, you say you add it in some of the mill streams with some of these processed wheat germs. Is that processed wheat germ milled out in the process as it goes on?

A. In the white flour, nearly all of the germ is milled out normally, and if it is left in, I might say by way of parenthesis, you are not leaving in enough B_1 to have any benefit by way of nutrition. But that is taken out, in the normal milling of white flour.

Q. Yes.

A. But we do not add this on the mill stream, I might say. We have a process used in the soft wheat mills and I think quite universally among manufacturers of selfrising flour, which is to weigh out the flour into a batch mixer, and then weigh your ingredients into that. We use that same type of batch mixer for the addition of this vitamin mix and the minerals. We take so much flour and then weigh in this mix that has been already premixed under strict laboratory control, with the processed wheat germ. But that is after the milling process has been completed.

359 Q. And then in your process there is in the finished product a processed wheat germ? There isn't any of it milled out or separated away?—In your flour that you put out for the special purposes.

A. We don't add any of the germ for the milling process.

Q. No; I understood you to testify a while ago that sometimes with the carrier it is added on the mill stream some time after the milling has been completed, and your particular mills add it after the milling—if I am wrong in that—

A. I am sorry if you misunderstood me, or I didn't state the facts correctly.

I think you have reference to my discussing the stability of thiamin chloride to bleaches. Now, I said that thiamin chloride is added after the milling process is complete. I tried to point out there that usually nitrogen trichloride and chlorine are added to flour during the milling process, and during that milling process they carry on their bleaching, carry on their oxidation very rapidly, and those bleaches are spent before our thiamin chloride is added, and therefore they are not significant with reference to added thiamin chloride. However, I did state, by way of
getting it into the record, that thiamin chloride in the
360 wheat flour is not destroyed by bleaching.

Q. Yes.

A. So if you were going to bleach your product and rely upon introducing it into the mill stream, it wouldn't hurt anything.

Q. I think the record is straight on that now, that you add it afterward.

A. Yes.

Q. We are a little confused, Doctor, about how much of Vitamin B_1 you actually add to your product.

A. Well, would it be satisfactory for me to put that in a brief?

Q. I would rather you would tell us. It is supposed to be in the record.

I believe you said—

A. I said we are putting somewhat more than 150, in order to make allowances. We are actually putting—and I don't have any particular objection to telling you—we are adding about 170 and then there is about probably 15 to 30 in the flour; that is, 170 international units per 6½ ounces and there is apparently from 15 to 30 in the flour with some variation there, that is making a total of from 185 to 200, where we are claiming 150.

Q. Going back to your testimony with respect to the stability of that Vitamin B_1 in the flour up to the time
361 it reaches the consumer, I don't believe I quite understood how you provided in your product for the Vitamin B_1 not to have an excessive reaction in an alkali solution. You are adding something to work with the baking powder, as I understand it. Will you explain that again, please, sir?

A. The calcium compound we are using in self-rising flour is monocalcium phosphate.

Q. Yes.

A. And we are using the regular self-rising formula that is in use by the mills, which is known to maintain a reaction around neutral.

Q. Yes, sir.

A. That will produce a biscuit with a p.h. of 7.2, which is a little over the point of neutrality.

Q. Yes, sir.

A. About 7.

Q. In the plain flour—

A. And I want to say this: We are using the self-rising formula as a base. Then we are super-imposing on that 25/100 per cent additional monocalcium phosphate in order to bring it down to, or right under the neutral point, which is 7.

Q. A p.h. of 7?

A. A p.h. of 7. 6.9 to 7.

Q. In this plain flour—

362 A. Then we are adding—I was going ahead with that.

Q. Yes, sir.

A. It is the custom in the mills selling family flour in the South where they don't sell self-rising, I might say it is almost a universal custom to add monocalcium phosphate, the usual amount added about .5 of 1 per cent. The primary reason for using that is to guard against an excess of alkalinity. And that is a pretty safe thing, if you have a baking powder, for instance, sort of leaning toward the alkaline side that will bring it over.

The acid doesn't make so much difference, but if you get too much from the alkaline side, then you will get a vile-tasting, vile-smelling biscuit. And when the housewife finds that sort of thing, it is always the flour and nothing else. They are the victims No. 1 of anything in the food line. And that is in the kitchen, too. So they always add that as a precautionary measure.

In our so-called plain flour, non-self-rising flour, you see,—

Q. Yes.

A. —we want to introduce the amount of calcium which various authorities thought was desirable, and which, incidentally, happened to be the same amount of calcium in the self-rising flour, by a fortunate coincidence.

363 But if we tried to introduce monocalcium into the plain flour without the acid ingredients, you naturally have a biscuit too far on the acid side to be satisfactory. It happens, roughly, dicalcium phosphate has about ⅓ the neutralizing strength of monocalcium if you would take .25 per cent monocalcium, and for the other .25 per cent its dicalcium equivalent, 3 times, or .75, you understand, you would have about the same amount of calcium in self-rising flour and the same neutralizing value as the average phosphated flour.

Do I make myself clear?

You see, by having that, at present, then you are not only supplying the calcium, but you are guarding against getting a baking powder biscuit too much on the alkaline side, which you might get if using a baking powder in plain flour, certain baking powders in plain flour.

Q. As I understand it, you are adding the monocalcium for the leavening effect, and the dicalcium phosphate to aid the calcium in there in larger quantities for neutritional values or from the neutritional standpoint.

A. Well, yes and no. The normal phosphate is .25 per cent—

Q. Yes.

A. I mean .5 per cent, and the normal phosphated
364 flour has been on the market for 15 years. I want to preserve that same neutralizing strength, but with that neutralizing strength in monocalcium, you haven't nearly enough calcium.

On the other hand, dicalcium has three times the neutralizing strength—I mean, ⅓ the neutralizing strength—of monocalcium; so you take ¾ dicalcium and ¼ monocalcium, and that combination gives you the neutralizing strength of the ordinary phosphated flour and the calcium content of self-rising flour.

Q. Then, as it is indicated now, you don't make a plain flour fortified or restored, but you make a phosphated or self-rising flour fortified or restored?

A. If you grant calcium compound as an optional ingredient, I do.

Q. Then that would come in as a neutralizing ingredient?

A. If you would accept them as optional ingredients, that would be flour; yes, sir.

Q. It would be flour, or would you rather add them under the self-rising flour and the phosphated flour?

A. This is anticipating a little, but we are going to ask on the basis of custom, that we continue the policy that has been in use 25 years, when it comes to the
365 definition of phosphated flour.

Q. Yes, sir; I understand that.

A. Further, I think if you want to, we can hold that for discussion at this time.

Q. Vitamin B_1 as a single optional ingredient, according to the ordinary practice today, is not added alone?

A. No, sir; not as far as I know. Except I believe there are some mills that can speak for themselves and I am not speaking for them, that may. I cannot speak for the general practice. I know as far as I am concerned, or the mills I have been associated with, the answer is No, to the best of my knowledge.

Q. This neutralizing effect is more or less necessary if the Vitamin B_1 is to be retained when the flour gets into commerce?

A. There is danger of loss, in my judgment, without that. That is a matter, perhaps, of opinion.

I might amplify that statement to this extent, sir, that there are, of course, other ways of bringing the proper p. h. without the use of ingredients I speak of. But I do think there is a certain optimum reaction and think there is no question but what there is a serious loss on baking if your p.h. gets up beyond a certain degree.

Q. What are those other ways of regulating the
366 p.h. to the desired point where you won't have too much alkali?

A. Well, I am not prepared to say. I know that solved our problem.

Q. Yes, sir.

A. I don't know as I would care to go into that, particularly.

Mr. Goodrich: Excuse us just a minute, please, sir.

Presiding Officer Willcox: Very well.

Mr. Goodrich: If anyone else cares to go ahead with the cross-examination, they may do so.

Presiding Officer Willcox: Does anyone else wish to ask any questions?

By Mr. Gilbert:

Q. You were talking about the addition of certain minerals, and it is one of your proposals that they be permitted as optional ingredients, and you mentioned you add the calcium by the addition of dicalcium phosphate.

A. Dicalcium phosphate and/or monocalcium.

Q. Are we to understand you are proposing as a mineral to be included in optional ingredients phosphorus?

A. No, I am not.

Q. Don't you get some into the product as the result of that ingredient you are adding?

367 A. Oh, yes; you do. And by using calcium compounds, that takes care of it as far as phosphorus is concerned.

It seems to be a matter of debate as to the adequacy of phosphorus. I am inclined to think it is a good source, but so long as anybody wants to argue on it, we have enough without bringing that up.

Q. Would you be opposed or in favor of phosphorus as also an optional ingredient?

A. I beg your pardon?

Q. I say, would you be opposed or in favor of the addition of phosphorus also as an optional ingredient?

A. I certainly would not be opposed to it. I think, if anything, I would be inclined to favor it, except that I think it involves useless controversy. We are taking care of it on the other side. If we weren't using the calcium compounds, I would be inclined to favor it. But, as I say, we are taking care of the thing as far as I am concerned. I think it is sort of a twilight zone. Question on that.

By Mr. Goodrich:

Q. Doctor, on this new flour you are putting out, are you selling it under any name other than flour, or how are you merchandising it?

A. Well, I have the name "Bi-Cap."

Q. Bi-Cap?

368 A. Bi-Cap, Incorporated; that is right.

Q. That is a trade name?

A. Registered in my name, personally.

Q. Are all of the—

A. Well, if you will let me go ahead.

Q. Yes, sir; excuse me.

A. I think I haven't quite completed the question. Then every miller that will agree to make the flour according to the directions I give him, is licensed to use the word "Bi-Cap." In other words, the registered word is "Bi-Cap," with simply a simplified spelling for brevity; so they all use that word in one design. But, in connection with that, each mill has its own brand name.

For instance, there would be—I am trying to think of one—"Red Rose Bi-Cap Flour" and "King Bee Bi-Cap Flour," and so forth, but we call it flour. And then, right under that name, "King Bee" or whatever it is, "high grade soft wheat flour to which has been added"—naming each ingredient. And then we also show for average daily use about 2 cups or 6½ ounces contain 150 units of B_1, 2½ milligrams anti-pellagra factor. We call it "Anti-pellagra factor" instead of nicotine acid. We wish we had a better name than that, because a lot of people down there would say that we are putting cigarettes in the flour—and 369 then the number of grams of calcium contained in it.

Q. In what way are you informing the consumer that this is a product for special use? Under what name; are you selling it under a name or depending upon other advertisements?

A. Well, selling it under the name of "Lily's Bi-Cap" and "King Bee Bi-Cap" and so forth.

Q. Yes, sir.

A. However, we are advertising it as white flour rich in B_1 and calcium.

Q. Don't you think it would be better if you standardized this product under the name of its own, rather than enter into this optional ingredient confusion under the white flour, which also laps over into the phosphated flour and self-rising flour?

A. No, sir, I most emphatically do not, for this reason: This is either good or it is not. If it is good, I think the Government ought to help us rather than retard us in getting consumer acceptance. I believe we have information to justify the fact that it is a meritorious product. Consumer acceptance is the real hurdle you have got to overcome. If you sell it too high, they won't buy it, or if you sell it too cheap, they will say it isn't worth a damn, and is just a new-fangled scheme to bamboozle 370 the public. The more you can bring out to them that it is not changing it essentially, especially from the standpoint of taste, the better it is, because when you begin to call it "Vitamin B, added" they think it is something like castor oil. When you get up against the public, you are really up against a job. If we can tell them that it is flour, and sort of slip it to them gently, it is one thing; but if we are going to call it something else, they are going to get suspicious.

Now, let me point this out, sir; I am glad you brought the question up because I want it in the record, that in our phosphated flour, we are not essentially altering the taste or baking characteristics, or the recipes that are used, as compared with ordinary flour. It is flour in every sense of the word, except that we have got something there to improve the public health. It is the sugar-coating on the pill, and if you begin to call it something else, then they are going to taste quinine, or something.

371 By Mr. Goodrich:

Q. Don't you think the consumer is entitled to know that he is getting a better product or will he depend upon the increased price to know that?

A. Yes, sir, and as long as we are putting something in there that costs $700 a pound, into something that costs 3 cents a pound, we are going to tell them about it, and furthermore, we are very anxious to have labels that, have a uniform system of labels, we want it to be thoroughly informative, except don't have it so long that nobody will ever read it, and we want you to hold everybody's feet to the fire on it; but I do think that we don't want you to try to hamstring consumer acceptance because it is a very difficult thing and something that I think is in the public interest. At least the British Government thought so enough to require it.

Q. What is the advantage of using the word "Bi-Cap Flour" over "Restored" Flour or something of that kind?

A. Well, if you want to call it "Restored" flour I don't know as it would make any difference. Of course that is a word that we have gone to considerable expense to copyright; it means, as you can see, it is derived from B-1 calcium and phosphorous.

It is probably obvious to you, but the main reason we didn't call it "Restored" flour is because it is not

372 a restored flour, and I don't believe Dr. Nelson would let us call it that. You see it contains actually about five times or I would say probably ten or twelve times, I would say, offhand, as much calcium as whole wheat, seven or eight times, anyway, and it doesn't contain quite as much nicotinic acid.

Q. Is there any way that we can get together on a common or usual name for the product other than these patented names? I understand some of the other manufacturers here also have registered names under which

they are selling a product with vitamins and minerals added, maybe not in the same way, and maybe not in the same quantities that you are adding them, but for the purpose of standardization, is there any word that we can get together on?

A. I just don't know, from the standpoint of absolutely calling it that, absolutely stating the facts, I couldn't call my product "Restored flour"; and I don't think that I would be correct in it.

Q. Is there any word that you could call it that would be reasonably descriptive, any adjective that you can use in connection with flour, any qualifying word at all?

A. The whole point is, it is flour so far as the housewife is concerned, its use, and preparation, and taste,
373 and everything else, is concerned, and I would regret having to put any sort of name there which would inspire suspicion.

Q. That would no more inspire suspicion, would it, than telling them that Vitamin B1, an anti-pellagra factor, and all of these others, are added on the labeling? You say that you put them on there and tell them about it in every case. I can't quite see what would be the difference in it?

A. They buy flour; they don't buy if "bleaching" was on there for a long time, but if you had to say "bleached" or if you had to go and give a lot of names, high-fallutin' scientific names, it would tend to suspect them, they are scared of change, you know, the public is scared of anything in the way of established custom. They get used to things in a long time.

Q. You have been selling this about three months, haven't you?

A. That is right. They have been selling flour about five thousand years, and I don't want to have to call it something besides flour, because that is what it is so far as consumer use is concerned, except that it is a better product.

Presiding Officer Willcox: I think that, it seems to me you have been talking at cross purposes a little here.
374 Are you speaking of any phrase that includes the word "flour" or are you speaking of an alternative name that might not include the word "flour?"

The Witness: We are built up here, I don't mean to seem, you know, antagonistic, in my answers to your questions, I am trying to make myself clear.

Now, we have got, for example, in these 23 mills that are using flour now, using our formula now, we have Kenney's Marsh King Bi-Cap flour, and that is long enough without having to spend something else in it. We have spent some investment in educating the people on the word "Bi-Cap," had it registered, and we don't want to drop it and the mills have an established brand name that they want to get associated with it, so as to capitalize on that, and not make it a common thing, so that they can benefit by their individual merchandising, don't you see.

Well, now, if we have to go and add anything else to it, that is making the name too long and getting confusing. I think that you can see from our willingness to have labeling that tells the truth, that we certainly have no desire whatever to conceal or cover up any facts, and in fact we want to brag about it. We think that we have got something good, something for the public benefit, great
375 benefit to public health, and of course we might have a little profit motive in there too, but at the same time you know, that is what it is, but I will submit, sir, that as long as we have got a product there that varies from flour only to the extent that it is beneficial, I don't see why we would have to have any modifying agency, as long as we have stated there in the label, any form that your Special Dietary Purpose Committee may decide.

Presiding Officer Willcox: You object to the addition of any adjective, even though the word "flour" is still included?

The Witness: Yes.

382 Q. What amount of nicotinic acid are you adding in your product, Doctor, or do you advocate adding it?

A. We are adding 2½ milligrams to 6½ ounces of flour.

Q. Is that equivalent to the amount in whole wheat?

A. Well, Dr. Elvehjem tells us that whole wheat would contain in the neighborhood of 5 milligrams, 6½ ounces, that is what it would figure out to, and now he said that probably in the neighborhood of 30 per cent of it was removed in milling, and information on it is very meager, and then there are a good many—I will start that again.

Now, there are some statements in the literature to the effect that excessive quantities of nicotinic acid are
383 bad, and that information is based largely on therapeutic information rather than a question of adding

it in dietary quantities. On the other hand, in view of that fact, and to follow the conservative policy, we have tried to add nicotinic acid in quantities not in excess of that found in wheat, so we went over it with Dr. Elvehjem and he gave me permission to quote him because there was not anything in the literature on it and that he thought the amount we add would be a helpful quantity and that I would be reasonably assured of not, or I could safely say that I was not adding the quantity in excess of wheat of that found in whole wheat.

Q. And any excessive amount likely would be harmful?

A. Well, you see, in the administration of these things for the cure of pellegra, or for the cure of any deficiency diseases, they feed them, or give the vitamins in very large doses, and many times your daily intake is many times the normal quantity essential for nutrition, don't you see, and it was in giving those very large dosages, that they had trouble, but on the other hand they did not know what the low point was where trouble might be caused, but certainly we would be safe so long as we stayed within the limits of the whole wheat content, and I have just tried to hold down and stay comfortably within that limit, and that was the basis of Dr. Elvehjem's suggestion.

384 Q. Is there a difference in the nicotinic acid content of hard and soft wheat?

A. There is very little known about it. The information on it is very meager. He told me that that was roughly around what wheat would be, and I think Dr. Nelson can tell you about the technique and that kind of thing.

I want to say this, and maybe subject to correction, as I understand it, there is not a well-defined assay method as there is in the case of B-1 and some other things.

Q. Can you tell us about how many average-size biscuits this 6½-ounce batch of flour would make?

A. Not meaning to be facetious, that is kind of like asking a question of how many halves in a whole, and saying it depends on the size of the whole.

You know, we used to have biscuits vary all over the map.

Q. I say, average size.

A. I don't know just what is an average size biscuit. Now, that is the truth. I am supposed to know a lot about biscuits, but that is a question that I could not answer. I just don't know. I will say this, that what you are getting

at is our flour which would make the same amount of biscuits as a flour without the optional ingredients
383 added, and without any difference in volume, substantial difference in volume, or taste, or appearance, or color, or any other quality.

Q. Upon what basis do we say that the average user uses 6¼ ounces of flour a day?

A. Take domestic sales of flour, and divide it by the population of the United States.

Q. That is the way that is done?

A. Yes.

Mr. Goodrich: I think that that is all.

Presiding Officer Willcox: Any more questions, Mr Campbell?

Mr. Campbell: I have no more questions.

Presiding Officer Willcox: Any other questions of this witness? (No response.)

(Witness excused.)

Mr. Campbell: I would like to call Mr. Wellinghoff. Whereupon

FRANK G. WELLINGHOFF was called as a witness for and on behalf of the industry and having been first duly sworn, was examined and testified as follows:

Direct Examination.

By Mr. Campbell:

Q. Will you please state your name, residence, and
386 occupation?

A. Frang G. Wellinghoff, St. Louis, Missouri. Vice President and Assistant General Manager of Baur Flour Mills Company.

Q. Just state briefly what your qualifications are?

A. With the exception of having spent a year and a half in the Army, I have been in the flour milling field since 1911, and I have been associated with three milling companies, and I have been with the present company for the past fifteen years.

Q. And the purpose of your testimony is to ask that wheat germ oil be permitted as an optional ingredient under the definitions and standards in Section 15.000?

A. Yes, sir.

Q. Will you proceed and state what your case is?

A. In the interest of producing a more flavorful and nutritional white flour, our Company nearly three years ago proceeded with a plan to incorporate the processed wheat germ. This was accomplished and since early in 1938 we have been restoring to white flour partially defatted and dehydrated wheat germ to the extent we found it favorable to the baking qualities of the resultant flour.

The advantages gained with the stabilized wheat germ are prevention of rancidity, conservation of the nutritional values; physical character permits proper milling
387 with the endosperm, and improved baking qualities resulting from equalization of the proteolytic enzymes, all with no harmful effect on the nutritional values.

Since the flavor value of the flour proved to be more appealing and desirable, and also because of the lack of the oil content of the wheat germ, about a year ago we began also to incorporate stabilized wheat germ oil. This we and many others believe increases the wheat flavor of the flour to a very desirable degree, and the inclusion of the oil has not affected the keeping qualities of the flour, as proved by having some of it in test storage for almost a year.

Our sales of this flour largely for bakery use were in proportion to our total sales of flour, about the same amount each year; 2½ per cent in 1938; 17½ per cent in 1939, and this far in 1940, 22½ per cent, with indications that the demand for it will continue to increase.

It might be of some interest that although we have not advertised this flour to the consuming public, we have quite a number of requests for it from consumers in widely scattered parts of the country. To my knowledge there are a number of other mills using one or both of the aforementioned processed wheat germ products.

We are also considering the possibility of adding these wheat germ products to whole wheat flour and in
388 the event that there would be a provision for it in the flour standards law, we likely would be inclined to market such flour. However, and since Dr. Strowd has already offered processed wheat germ as an optional ingredient for use in white flour, I now only offer processed wheat germ oil as an optional ingredient for use in white flour.

By Mr. Campbell:

Q. How long did you say that you have been marketing this product?

A. Since early in 1938.

Q. How do you put it on the market? Under what description or trade name, or what?

A. We have a trade name for it, and in connection with the statement that there is wheat germ included in flour.

Q. When you say that you have been marketing it for about three years, you mean by the addition of this ingredient which you describe as wheat germ oil?

A. Well, until late in 1939, we marketed the flour with only the processed wheat germ and since that time we have incorporated both and separately. The processed wheat germ and the processed wheat germ oil.

Mr. Campbell: That is all.

Cross-Examination.

By Mr. Goodrich:

389 Q. Mr. Wellinghoff, you understood that Dr. Strowd offered processed wheat germ as a carrier for his product?

A. Yes, sir.

Q. You are using it singly, by—in what way? How do you get it back in? Mill certain streams back in, or what?

A. We feed it into the process of milling at a certain stage of the milling.

Q. At which stage?

A. We feed it into the first middling stream after the reduction.

Q. Your firm is a milling outfit?

A. Strictly millers.

Q. Is this product sold under any special name? I didn't get that part.

A. Yes, sir, it is available in commercial trade.

Q. Under what name, just trade names?

A. Our product, or the processed wheat germ?

Q. Your product?

A. It is sold under a trade name.

Q. There is no such thing as wheat germ flour?

A. No, sir.

Q. What is the trade name it is sold under?

A. The trade name is "Holwhite, Wheat-Germ-Included Flour."

390 Q. Now, about this wheat germ included oil, is that as a carrier, or added directly into the mill stream?

A. Directly.

Q. In a liquid form?

A. Yes, sir, in its own form.

Q. What amount is added?

A. Well, we experimented with various amounts and we are now adding it to the extent that we think makes the flavor most desirable.

Q. Do you regulate that by a tasting process or what?

A. We have come to the conclusion as to the amount that we want in the flour, for the benefit of a desirable flavor.

Q. When your product is finally completed, is there more processed wheat germ than there was in the original wheat, or not?

A. Well, there isn't the same proportion that there would be in an equal amount of whole wheat.

Q. Is there more than that?

A. No, there is less than its proportion in an equal proportion of whole wheat.

A. Also less.

Q. And the combination of the wheat germ oil which
391 you add, and the wheat germ oil appearing in the wheat germ which you put in there, how does that line up?

A. Well, that probably in combination would also be less than its proportion in an equivalent amount of whole wheat flour or whole wheat.

Q. What recommendations do you have as to a minimum and maximum amount of whole wheat germ to be added back?

Mr. Campbell: You mean whole wheat germ oil?

Mr. Goodrich: No, the whole wheat germ, processed wheat germ, I mean.

The Witness: We like to add it to the amount that it keeps the flour favorable in baking quality.

By Mr. Goodrich:

Q. We have to know what that amount is, sir. The record should show that.

A. The amount that we add?

Q. The amount that you recommended as reasonable amount to be added?

A. Well, I would say at least half of what would be the proportion in the same amount of whole wheat.

Q. What method of determining whether that amount is in there, do you have?

A. Production figures determine that.

Q. What amount of fat is present in flour used for baking bread, usually?

392 A. In ordinary white flour?

Q. Yes.

A. I am not qualified to say that.

Q. How much in the completed loaf?

A. How much fat?

Q. Yes.

A. I am not equipped to say that, either.

Q. What do you sell this wheat germ oil flour, or wheat germ oil bread for? What do you represent it as, having nutritional value?

A. It is also the processed wheat germ and oil in combination. We sell that to have an enhanced wheat flavor.

Q. That is all of the advantage that you claim for it, just the flavor?

A. We also state that the wheat germ is included with its natural nutritional values.

Q. Do you inform the consumer what those natural nutritional values are?

A. Not to any extent. Yes, we enumerate them.

Q. What are they?

A. Those would be vitamins B, G and E, minerals.

Q. You represent all of that coming from this small amount of wheat germ oil and wheat germ process?

A. Yes, sir, we merely claim its portion, that the 393 wheat germ is included with its nutritional values.

Q. You say that about half of the amount of the processed wheat germ and wheat germ oil is included in your product as appears in the whole wheat?

A. Yes, sir.

Q. That would be about one per cent of wheat germ, and about 1/10th of one per cent of the wheat germ oil?

A. Yes, sir, that is right.

Q. Now, how does that compare with the amount of fat which would ordinarily be present in the completed loaf do you know that?

A. No, sir, I don't know that.

Q. Has your company made any experiments of any kind as to the nutritional value of this product?

A. No, sir.

Q. Do you have available for introduction at this time any results of such experiments?

A. The processor of these wheat germ products was here

yesterday, but was called away and the proper affidavits may be obtained from him if it is so desired.

Q. You don't have the data now?

A. No.

Q. You brought out, I believe, that you buy this processed wheat germ and wheat germ oil and then add it back in. You don't manufacture that yourself?

394 A. That is right.

Mr. Goodrich: I move that we take a recess for lunch at this time. It will take me some time to get together on this product; it is a new product, and I move we recess, say, until two o'clock.

Presiding Officer Willcox: We will recess until 2:00.

(Whereupon, at 12:30 o'clock p. m., a recess was taken until 2:00 o'clock p. m. of the same day.)

395 Afternoon Session.

(The hearing was resumed at 2:00 o'clock, p. m.)

Presiding Officer Willcox: We will proceed.

Whereupon

FRANK G. WELLINGHOFF, the witness at the recess, resumed for and on behalf of the industry, and having been previously sworn, further testified as follows:

Cross-Examination by Mr. Goodrich (Resumed).

Q. Mr. Wellinghoff, do you feel qualified as a chemist to tell us what happens to this wheat germ oil when incorporated into the flour?

A. No, sir, I am not.

Q. You are not a chemist?

A. I am not a chemist.

Q. Can you qualify as a nutrition expert as to the value of the wheat germ and the wheat germ oil when added to the flour?

A. I cannot.

Mr. Goodrich: I think that that is all.

Redirect Examination by Mr. Campbell.

Q. Mr. Wellinghoff, this testimony that you have been putting in is on behalf of your individual mill, is it
396 not?

A. It is, sir, the particular testimony.

Presiding Officer Willcox: Any other questions of this witness? (No response.)

(Witness excused.)

Mr. Campbell: I would like to call Mr. Hardenbergh.

Whereupon

C. M. HARDENBERGH, was recalled as a witness for and on behalf of the industry, and having been previously sworn, was further examined and testified as follows:

Direct Examination by Mr. Campbell.

Q. You have been sworn?

A. Yes, sir.

Q. Mr. Hardenbergh, have you any remarks to make or recommendations to make with respect to Vitamin D, as an optional ingredient?

A. Yes. As a representative, not of the Millers National Federation, but speaking as an officer of the Commander Larabee Milling Company, we wish to have included as an optional ingredient under this title 15 or 15.000, Vitamin D. We have been putting Vitamin D in our white flour since back in 1935. The trade on it during the first few years
397 was not very much but it has gradually grown; during the last two years we have shipped between 50,000 and 60,000 barrels a year and it is increasing more rapidly at the present time. That is, those years are what we call our fiscal milling year, and at the rate we are going now it will show a considerable increase this year if it keeps up.

Q. How do you ship that, or under what name do you sell it?

A. We ship it mostly under the name of Sunfedd Flour. When we sell it we the bakery trade or the bakers as consumers, and we sell a certain number of barrels of flour, and they have the option either of taking flour, either our regular brand of flour which has no Vitamin D or they can take the flour with Vitamin D added under the Sunfed brand at a differential in price.

Cross-Examination by Mr. Goodrich.

Q. In what form is Vitamin D added in your practice?

A. We buy it and it is already mixed with wheat flour so that we add the wheat flour with the Vitamin D in it to our flour, in the process of milling.

Q. Do you know what the form of the Vitamin D is before added to the wheat flour carrier?

A. We put this Vitamin D in our flour under a
398 license agreement with the Wisconsin Research Foundation. Mr. Scott of the Foundation is here, and he is an expert qualified to testify in connection with this Vitamin D, and I can not answer technical questions. I would rather say I don't know, and I am sure that Dr. Scott can give you the information that you want from the scientific point of view.

Q. Is there a label declaration of the presence of the Vitamin D now?

A. Yes, sir.

Q. Where does that appear on the label?

A. It appears under the brand of "Sunfed."

Q. In what form?

A. I think it now reads that it contains 380 units per pound.

Q. That is per pound?

A. Yes.

Mr. Goodrich: I think that that is all.

(Witness excused.)

Mr. Campbell: I would like to call Dr. Scott.

Whereupon

DR. HENRY T. SCOTT, was called as a witness for and on behalf of the industry and having been first duly sworn, was examined and testified as follows:

399 *Direct Examination by Mr. Campbell.*

Q. Please state your name, residence, and occupation?

A. Henry T. Scott. Residence, Madison, Wisconsin. Present position, Director of Biological Research for the Wisconsin Alumni Research Foundation.

Q. Your testimony in this case is given on behalf of what company or organization?

A. The testimony that I shall give will be in behalf of

our two licensees that are purchasing or using Vitamin D under the Steenbock process—that is, namely: the Commander Larabee Milling Corporation, Minenapolis, Minnesota, which puts out Sunfed Flour and the Quaker Oats Company of Chicago, Illinois, which adds or enriches farina with Vitamin D which is also under consideration at this time.

With your permission, I will state my qualifications.

Q. Go right ahead.

A. In 1925 I was granted the Bachelor of Science degree in agricultural chemistry, specializing in agriculture from the University of Wisconsin.

I was granted a Master of Science degree in 1927, and Doctor of Philosophy degree in 1929. During that time I specialized in bio-chemistry, inorganic chemistry and medical sciences.

From 1925 to 1928 I was assistant in the University of Wisconsin in the Department of Agricultural Chemistry and I was instructor from 1929 to 1930, Chemist at the Wisconsin Alumni Research Foundation from 1930 to 1933 and Director of Biological Research since that time.

My researches in this field have dealt largely with Vitamin D, biological chemistry, chemistry metabolism and other related fields.

I have had publications in the Journal of Biological Chemistry, Food Research, Poultry Science, and other technical journals.

At the present time I am a member of the American Public Health Association, a Fellow, rather, of the American Chemical Society, American Dairy Science Association, and the American Congress of Physical Therapy.

At the present time I am also Chairman of the Committee Bio-Assay foods for the American Public Health Association and was formerly a member of the Committee on Nutritional Problems, and Chairman of the Committee on the Assay of Vitamin D milk.

I should like to make one or two—or preface my remarks by stating just what the Wisconsin Alumni Research Foundation is, and what its purpose is.

It was organized in 1925 to promote, help and aid in the research at the University of Wisconsin. Its charter as defined permits it to take over patentable ideas from the University professors, secure patents thereon, and when the patent is finally commercialized, to the point

where it produces revenue, the income from the revenue is used for research at the University of Wisconsin.

Among the patents which we hold are the Steenbock patents which have to do with the activation of foods and pharmaceuticals for the production of Vitamin D.

In addition to this, the Foundation maintains a control laboratry, and I have charge of that laboratory and also charge of public health and public relations angles as they may relate to technical matters.

One of the things which we attempt to do is guarantee the potency of products licensed by us and to aid the licensee in every way to maintain the potency of his product and also to control insofar as is possible advertising claims so that no unwarranted claims will be made on the product.

I think that that gives enough information for the record as to our interest in this problem, and our two licensees which we are attempting to represent today.

I would just like to quote, in discussing the first part on "Vitamin D regulates the metabolism of calcium and
402 Life" which is a publication, Year Book of Agriculture, for 1939, issued by the U. S. Department of Agriculture.

On page 255a:—this was written by Frederick W. Irish, Associate Chemist, Food and Drug Administration:

"Vitamin D regulation the metabolism of calcium and phospherous in the body and thus is concerned in the proper formation of bones and teeth. The mechanism by which Vitamin D functions has not been determined with finality, but it is believed that in some way it facilitates the absorption of calcium and phosphorous from the alimentary tract. It does not decrease the minimum requirements for calcium and phosphorous, however, and can not produce good retention of these minerals in a person who requires too little of them.

One more quotation, just a statement, and this is one by Henry C. Sherman in the same text. I am referring to page 187:

"Calcium is the outstanding element of the mineral matter which gives shape and permanence to the body's framework, which endows our bones with strength and our teeth with hardness that they may need."

One more statement, from page 188:

"Of the relatively large amount of calcium that
403 belongs to our bodily structure, 99 per cent or so is

contained in the skeletal system, the bones and teeth with their immediately attached connective tissues."

Now the necessity for Vitamin D in commonly used foods—and it has been our policy since we started to give consideration to three of the basic foods, milk, bread and cereals—there is no question but that milk probably predominates because of its ideal balance of calcium and phosphorous. However, we have been engaged in the promotion of Vitamin D milk for the past ten years, and of all of the Vitamin D milk which is sold today, only 6 per cent of the total is so enriched with Vitamin D that is not all by our process, but by other processes which are sponsored by other concerns as well. Therefore, there is a definite need for Vitamin D in some commonly consumed foodstuff, because man at the present time is not getting sufficient Vitamin D, because of the lack of sunshine. We don't get out in the sun.

Today there might be good sunshine here in Washington but the time when the sunshine is effective we are in here. We are clothed, our mode of living and everything tends to reduce our opportunity for securing this factor.

404 Now, the Vitamin fortification of foods has been going along and has been rapidly gaining favor and support by nutritionists, who have studied the facts at their command. Although many new factors have been isolated in the past five years, few, if any, have received the great attention that has been given to Vitamin D. This seems to only be just, for several reasons; first, as I cited, because of the scarcity of Vitamin D in nature.

Practically everyone will admit that the best source of Vitamin D which we have, which may be obtained in a common food, is the yolk of the egg, and in dairy products. In the yolk of the egg, if you wanted to get a good supply, you probably would have to eat eight to ten or twelve eggs a day, depending on how the hens were fed.

In milk and dairy products, cheese, butter and so on the amount is very small.

I would now like to refer to a paper from the Journal of the American Dietetic Association, Volume 11, No. 2, page 119, for July of 1935. This is entitled "Lack of Vitamin D in Common Foods." The author is Joseph Coffin. Dr. Coffin has made a study and analysis of the Vitamin D content of foods. This was in 1935, and take bread, for example, white bread—it requires 254 servings

of white bread to give you 150 U. S. P. units of
405 cod liver oil, which is equivalent to half a teaspoonful.

The same figure holds true for whole wheat.

Take lettuce; if you want to get the equivalent of half a teaspoonful of cod liver oil you would have to have 4,010 servings, and so on.

There are forty foods listed here, in which these data are given for. I am not going to take the time to go into this in detail, but this reference is one I would like to just have in the record for citation.

Mr. Goodrich: Do you want to incorporate this pamphlet into the record, or do you just want to have the reference?

The Witness: I think just the reference to the article will suffice.

Now, to verify the fact that the sunshine is not effective so far as Vitamin D is concerned, you only have to consult with the Weather Bureau, and the records, and you will find that the daily hours of sunshine is very small, in most of our cities, it would really surprise you when you start to look them up, but when one studies the records of the amount of Vitamin D which is distributed by sunshine and figures in the winter time it is much less than it is in the summer time, it is very easy to see why we do not yet much, and then consider our vacation perhaps is only two weeks and then maybe we get too much.

406 Now, while most attention has been directed in the past to the correction of Vitamin deficiencies in the diet of infants and growing children, little, if any, attention has been paid to the adult. Indeed, the majority of the articles that you might have read in the past on this subject give little space to this phase of nutrition and passes it lightly by saying, "Well, the adult doesn't need Vitamin D or if he does need Vitamin D the requirement is not very high," and it is pretty hard to get anybody to state that the adult does not need Vitamin D.

Now, of course, I think that this has been changed to a large extent because while this order has not been considered, I read in the Federal Register for September 5, 1940, on page 3365, under 125.03, label statements relating to vitamins, I note in there that they have for Vitamin D 400 U. S. P. units for any person, irrespective of age. I think that that is a fine thing, because it recognizes the need for Vitamin D in all ages.

Now, I will grant that this is subject to consideration,

and is open for public hearing, starting on October 7, but I think that this point regarding Vitamin D as a necessary accessory food factor for individuals of all ages, is a mighty fine thing, because it is readily recognized in infants and growing children that Vitamin D is essential
to cause a proper absorption of calcium and phos-
407 phorous, absorption and retention, I might say.

Now, having reached adulthood, the physician still recognizes the need of the human organism for the minerals calcium and phosphorous.

Sherman says adults should receive point 68 grams of calcium per day and point 88 grams of phosphorous daily. This order in the Federal Register for September 5 which considers vitamins and minerals I note says 750 milligrams—that is point 75 grams; and the same figure is given for phosphorous. I will not quarrel with that. That is a very conservative figure, but it does show the necessity in the adult or in any individual for calcium and phosphorous.

Now, these minerals have a variety of duties to perform. For instance, calcium, outside of its most obvious function, bone formation, finds many uses. With the exception of dental enamel, bone is not fixed and constant, but is always undergoing decomposition and restoration, so that the constituents must be replaced readily.

Calcium ions have a further function of decreasing membrane permeability, thus antagonizing the action of sodium and potassium ions. The latter increase permeability, thus increasing the tempo of life of the tissues, and so the rate of destructive metabolism is allowed to go to dangerous stages unless checked by calcium ions.
This function also applies to capillaries.
408 Some evidence has been produced to the effect that
calcium in some way is concerned with the transformation of chemical energy into muscular contraction.

Calcium is also necessary in the transport of nerve impulses from one neuron to another.

Calcium is also essential in the blood clotting process, and for the coordinated functioning of the heart.

In the scheme of things, phosphorous likewise plays a prominent role in regulation of acid base reactions, acting as a buffer in the fluids and tissues. In muscular contraction, phosphorous in combination with carbohydrate forms a hexose phosphate which takes part in the process of muscular contraction; this process appears also to be

involved in the absorption of fat and carbohydrate from the intestine and the resorption of glucose in the renal tubules. In the form of phospho creatine, phosphorous enters into the process of propagation of nerve impulse and is believed to be the source of energy of contraction in muscle.

Right here I would like to quote from an article which just appeared in the Journal of Nutrition, by Carl H. Krieger and Harry Steenbock, Volume 20, page 125, No. 25, for August, 1940. It is entitled "Cereals and Rickets." Now, this article, the main item which it points out is the fact that the phytic acid phosphorous which
409 we have not referred to but which is or may be a component in the diet and certainly is a part of the cereal and also the inorganic phosphorous were considerably improved when Vitamin D was present, and when it was absent a lot of this phosphorous was lost, that it was not absorbed or not utilized, and I just would like to cite that as a technical reference which is of importance in this discussion.

Now, the summary which I have given as to the functions of the two mineral elements indicates at once their importance. However, all of this discussion presumes that the minerals, if supplied in proper amounts, at all times are properly absorbed.

Absorption is governed by several factors, such as pH, hydrogen ion concentration, Vitamin D content, and the bile. Obviously the vitamin ranks first in importance, because thousands of balance experiments on animals as well as growing children indicates the terrific loss of mineral elements by way of excreta when Vitamin D is lacking, even though the minerals were supplied in optimum amounts, and I would like to say that I have had the opportunity while associated with Professor E. B. Hart, at the University of Wisconsin, of conducting many of these experiments on various types of animals, all the way from the rat to the dairy cow.

410 While it is recognized that acid base relation, as well as influence of the enzyme phosphatase is important, the part played by Vitamin D cannot be minimized if, in addition to the infant or growing child, the adult is to properly metabolize the daily intake of calcium and phosphorous.

Because of its scarcity in nature, nutritionists are more and more coming to recognize that Vitamin D should be

supplied in the food, in a food that is consumed regularly, in a food that can supply this factor to the great mass of our population at no extra cost, as it is all too evident that the deficiencies that occur are in those families on low income that cannot afford to buy cod liver oil, Viosterol, or a host of other concentrates that are available.

So important is this subject becoming that the American Institute of Nutrition at their annual meeting (Toronto, Canada, April, 1939) in a symposium considered the fortification of foods with vitamins and minerals. Among the papers presented, Dr. Lydia J. Roberts of the University of Chicago had the following to say:

"Although the deficiency of calcium is best met by milk, I should not object to a judicious addition of both calcium and Vitamin D to bread and cereals, espe-
411 cially in localities where milk consumption is low."

Very brief abstracts of this symposium appeared in the "Journal of Nutrition," Supplement 17, 22, June 10, 1939.

A recent editorial in the American Journal of Public Health (29, 792, July, 1939) entitled "Restoring Lost Vitamins to the Diet" well appreciates the seriousness of present day dietary vitamin deficiencies. A quotation from this editorial, taken from Circular 507, U. S. Department of Agriculture, assumes utmost importance.

"Recent investigations of approximately 4,000 food records among families in 43 cities have shown, furthermore, that fully half of these diets needed improvement. Perhaps the most significant of the dietary faults discovered was a lack of sufficient calcium and Vitamin A. Many of the diets were also inadequately provided with Vitamin B-1 (thiamin), Vitamin C (ascorbic acid), and iron. No data was given in this report on Vitamin D, but many observations have indicated a paucity of this important food factor in the average family diet."

Now, this above survey was collected by the Bureau of Home Economics of the U. S. Department of Agriculture, and the investigators were Stiebling and Phipard.

The survey just referred to is an excellent example
412 of the deficiencies occurring in employed wage earners, yet if one investigates the diets of families on relief, no provision is made for Vitamin D in the majority of the diets, and if milk is provided, it may not always be enriched with Vitamin D.

In the Pacific Science Congress, Berkely, California,

August, 1939, nationally known speakers stated that th
greatest danger today was that the public might receiv
too few and not too much vitamins.

Obviously, if the national health is to be maintaine
the American public should get not merely its minimu
requirements but its optimum vitamin requirement.

When all factors are taken into consideration, Vitami
D is the one preeminently and notoriously deficient
American diet, and always will be unless more general us
of Vitamin D food is received universally and automat
cally by our adult population.

From the host of functions of calcium and phosphorou
in the human body, it would be safe to conclude that
regular intake of vitamin D by the adult is highly desi
able if the body is to properly metabolize these miner
elements.

In summarizing it may well be said that so far as th
adult is concerned, not only is calcium desirable but vitall
necessary. In such periods of physiological strain a
413 pregnancy and lactation, the demands are in exces
of the normal. Fractures in adults heal only as
result of the mobility and state of flux that calcium i
undergoing. In such conditions as osteomalacia, calciu
salts are of paramount importance.

As has been shown by Stiebling, the average America
diet is in default when calcium is considered. Lack o
Vitamin D in the diet does not permit even a fair utiliza
tion of the meager amounts of calcium that may be presen
thus predisposing the adult to a very critical border, an
as Dr. Edwards Park has weel said, "Vitamin D is neces
sary for optimum calcium utilization."

Not so long ago I had the opportunity of abstractin
an editorial and rather than abstracting it I have take
it in its entirety because it relates to this question o
adult needs for calcium and adult needs for Vitamin
and perhaps in an indirect way.

It is entitled "Senile Osteoporosis" and is taken fro
the Journal of the American Medical Association, Volum
112, No. 5, February 4, 1939, page 434:

"Protracted mineral starvation may well be the princi
pal cause of disability associated with the general osteopo
rosis commonly present in elderly persons. The basi
dietary requirements for minerals of infants, and to
414 slightly lesser degree of older children and adolescents
have been established with reasonable accuracy. Lit

little scientific interest has been shown in the problem of vitamin or mineral nutrition for the adult. The theory that protracted deficiencies in basic nutrition resulting from poor dietary habits may impair the health of the adult and contribute to the factors which produce disabilities commonly attributed to "old age" has rarely been postulated. Orthopedic surgeons have long been aware that many older patients show extreme degrees of demineralization of the skeleton, as demonstrated by the roentgenogram. Many adults develop this osteoporosis before they are 50 years of age. A still higher percentage show this skeletal deficiency by or before the age of 60 years. Symptoms produced by moderately advanced generalized osteoporosis may be so indefinite that the skeletal demineralization is unrecognized as a cause of the patient's lack of vigor or premature senescence. Ghormley, Sutherland and Pollock indicated recently that an increased number of patients are entering the clinics of the country with severe disability produced by pathologic fractures of vertebral bodies which, weakened by the loss of their lime salts,
were not able to withstand the stresses and strains of
415 the ordinary day's activity.

Gradual demineralization of the skeleton over a period of many years may result in pathologic changes in the kidneys or other vital organs and hence affect unfavorably the general health of the patient. It is sometimes forgotten that the bones are alive, that there is a constant interchange of the mineral salts in the bones of all living vertebrates. Generalized osteoporosis in the adult can be explained only on a basis of a chronic or intermittent negative mineral balance over a period of many years.

Maxwell has shown that acute calcium-vitamin D starvation in the adult is the etiologic factor in osteomalacia. Generalized osteoporosis, which produces varying degrees of disability in the aged, may therefore well be merely a chronic, insidious and often subclinical form of osteomalacia. Some evidence has been offered which indicates that adults who live in civilized countries and who eat foods that are specially prepared and refined may not have in their diet the basic requirements of calcium or of vitamin D.

I am not going to quote this in its entirety, but that is the first part of the editorial. I think that that is
416 sufficient to convey the idea which I want to, with respect to the adult.

Now, obviously, it would be a simple matter to go on and cite many more references. I don't believe that that is necessary. We have been fortifying foods with Vitamin D and particularly the products farina and Sunfed flour for the past five years or more, and they are products which are standard. However, I think in any order which is promulgated or written that Vitamin D should be included as an optional ingredient in all of the flourstuffs defined.

I am not saying that, perhaps, anyone wants to add them to all of these flourstuffs which are to be defined in this order, but I think the door should be left open so that we will not have to come back and call a rehearing or attempt to get an amendment which will require the time and effort and energy of all of us. I think that it is well enough established so that the Vitamin D should be considered an optional ingredient in any flourstuff which is defined today, and it certainly is well enough established, and I would suggest that in the food to which Vitamin D is to be added, that when the order is promulgated that it could be added as a concentrate extracted from the natural sources, or as a concentrate produced by ultra violet in radiation or a concentrate activated 415 by other processes, and that any of these are good, they are all good, that the type or the way which vitamin D is to be added should not be limited.

If the Vitamin D is to be added to flour, certainly there should be a minimum standard. I have not attempted to set any hard and fast number of units here but I do not think that a flour should be recognized as activated by Vitamin D unless it contains a minimum of 200 U. S. P. units per pound. It could well be raised to 300 units per pound.

Likewise with respect to farina, where we are thinking more in terms of ounces, I believe the minimum standard should be not less than 200 U. S. P. vitamin D units per ounce for farina, because that is to be used as a breakfast food. I think that the amount or the serving of one ounce should be significant.

Now, in concluding, I would like to say that there are many more references which could be cited. I think if one reviewed the number of technical papers and articles which have been written on Vitamin D today it probably would go up somewhere between 20,000 and 25,000 articles. They don't all deal with the subject matter which we are talking

about today, but it just shows the great amount of literature which is accumulated in this field, and with respect to this whole subject of vitamin fortification and vita-
418 min restoration.

The number of papers which any of my colleagues—I wouldn't say colleagues, but brothers of science that might be citing them later on, I think would be practically in the same category, and in order to save time I am going to conclude my remarks, and if there are any questions I would be glad to attempt to answer them.

Mr. Campbell: I have nothing further.

Cross-Examination by Mr. Goodrich.

Q. Dr. Scott, we need to have cleared up for the record what you mean by Vitamin D concentrates.

A. Yes. Now, I might say that in order to clear this up, that you asked a similar question of Mr. Hardenbergh, I believe, with respect to the type of Vitamin D.

Q. Yes, sir.

A. Well, now, Vitamin D is prepared by another licensee of ours, the E. I. du Pont de Nemours, who prepare it for Commander Larabee in flour, so that they get it all from du Pont and all they have to do is feed it in the flour. That is crystaline Vitamin D. As a matter of fact, the concentrates which I referred to, you have on the market today, concentrates from natural sources. By that I mean, extracted from cod liver oil or other fish liver oils.

419 You have concentrates known as Vitamin D-3, and you also have concentrates of irradiated cholesterol which is sold on the market as Delsterol, and those are animal products.

Then from the plant you have irradiated ergosterol and that may be obtained from yeast and molds. That is a concentrate which may be put up in flour or put up in oil or put up in butter fat, any way you may desire.

Then you have concentrates of activated ergosterol which is not necessarily produced by direct irradiation—General Mills has a process for activation of ergosterol which can be added to foods or milk, or anything, and then there are other processes with which I am not so familiar.

Standard Brands have irradiated or activated yeast which should be a good carrier for flour, an irradiated yeast, I should have said, so generally that is the ref-

erence that I have to concentrates of Vitamin D, and in order to assure concentrates you have to get something that contains a sterol or higher alcohol, for the reason that a lot of food can't be directly irradiated because they don't contain this sterol, so you have to extract the sterol from the place in which it is carried and activate it by ultra violet light or sunshine or electrodeless discharge, or in one of the many methods which are used, but all of
420 those are satisfactory, they are all highly refined products, and all marketed and standardized and put out by very reputable companies.

Q. Are they all neutral in taste and color? Do they do anything to the flour?

A. No, there is nothing which they do to the flour. They are practically tasteless, you can take a gram—that is, one quarter of a teaspoonful of irradiated ergosterol and put in there 17 million units of Vitamin D and when you consider they only put 380 in a pound of flour, it is a small amount, and you might wonder about irradiated yeast, you can incorporate irradiated yeast in flour, and the concentration of Vitamin D is so high that you will not even notice that, it makes a very good carrier for flour or for any food, in fact.

Q. What is the potency of pure Vitamin D in units per gram, if you know?

A. Well, I wouldn't think—I think it is about 40 million.

Q. What potency in Vitamin D should a product have in order to be called a Vitamin D concentrate to which you have referred?

A. The figures are getting up pretty high now. I know it is customary for our licensees to manufacture concentrate, like General Foods, Standard Brands, and du
421 Pont, who put these concentrates out, to dilute them as it manufactures them, but a concentrate of Vitamin D is something that you think of containing at least as much as a million units or two million units per gram, and it might be any potency but I think of a concentrate containing at least one million units.

Q. That is what you mean in your testimony with respect to Vitamin D concentrates?

A. And of course the concentrate is going to be diluted and the Council on Pharmacy and Chemistry of the American Medical Association accepts Vitamin D in fish liver

oils or reinforced fish liver oils that are reinforced with activated ergosterol.

The highest potency they will accept is 10,000 units per gram. That is not a concentrate, that is an ordinary product, with your doctor will prescribe or you will purchase at the drug store.

Now, I would say that you would have to have a hundred times that to be talking in terms of concentrates. It is just a general thing, and it is very hard to say but it should be high.

Q. Now, you have recommended this Vitamin D for all of the products recommended in the proposal?

A. That is right.

Q. And they are not now used in any except the
422 plain flour and farina.

A. Just the two I have mentioned, but I feel that the way this question of restoration is developing, that we don't want to add Vitamin D promiscuously, our policy has been the basic foods, milk, bread and cereals, and we feel that the way should be left open for the addition of Vitamin D to the other flours which may be defined, so that we may save time.

Q. Even if it is a specialty flour such as whole durum wheat flour or semolina?

A. Yes, I see no reason for restricting it, perhaps it never would be used, and if you ask me I might not recommend it.

Q. If you go too far you would be adding it to everything, I thought the position you took at first was to be added to a basic food, and flour being a basic food, that was the place to put it, rather than adding it promiscuously to every product.

A. I don't recommend adding it to every product, but what I believe is that the way should be left open in case you and I and the rest of us, we don't know what is going to happen, we can't predict from day to day what is going to happen. If five years ago somebody said to you that the American Medical Association was going to okay the addition of Vitamin B to cereals and flour, you probably
423 would be challenged, and yet they are doing it today.

And that is just an example. We don't know, and the time this order is written, maybe conditions will have changed.

Now, the fact that we leave the way open to add Vitamin D to all of these things doesn't necessarily mean that we

are going to, it means that we have an opportunity to, we may save time by doing it. And generally if it is going to be added it is going to be added to something in a mass, which the mass of the poor people, the low-income people, that don't buy cod liver oil, you have got to give it to them and put it on a platter to them, it has got to be there.

Q. I don't see your point, and the point being made by some of the other witnesses this morning, that this is going to go so freely to the lower income groups. The flour unquestionably is a higher-priced product, it is sold for specialties, for special dietary uses, and that being the case it carries a higher price, and it is not as likely as the impression left in the record this morning that it will reach those classes, is it?

A. The majority of the flour which is now enriched with Vitamin D is used to manufacture bread, Sun-Fed Bread. Now, if you can educate the public that don't buy Vitamin
D during the winter time, where they have youngsters
424 and don't buy Vitamin D milk, you have done something, and now when it comes to Vitamin D milk your codes and marketing regulations says that those milks and fresh milks shall be sold at a premium in order to prevent strikes and price wars and so on. There isn't that opportunity in bread. I don't think that there is because it is not under such a highly organized group in its distribution.

So that I think that any extra costs, I don't know what the bakers will sell it for, whether they get a cent more a loaf for it or sell it at the same price or give them a bigger loaf or what, I am not familiar with that distribution, but the majority of your Sun-Fed flour goes to bakers where it is made up into bread. It can be purchased by the consumer, but the price there is not any more than 5 cents for a 48 pound bag, if it is that. The cost is very small.

Q. I take it that Vitamin D is known under that as its common and usual name, Vitamin D?

A. Yes, sometimes it has been referred to as the Sunshine Vitamin, although if you use the word "Sunshine" the Council on Foods requests that you put it in parenthesis.

Q. What would you say is the known and usual name?

A. Vitamin D, there is no question, but it sometimes
425 referred to as the Sunshine Vitamin, inferring that you can get Vitamin D from the Sunshine at the proper time of the year when the sun is bright, and so on.

But it is known commonly as Vitamin D, the "Rickets-Preventing Vitamin," and so on, and known under all of those terms.

Q. Do you think that it would be in the interest of consumers to have a label declaration of the presence of Vitamin D?

A. Yes, I certainly think so, the Vitamin should be declared, the source and the unitage.

Q. Both the source and the units?

A. Probably the source isn't so necessary, you can declare the Vitamin and certainly the unitage. Of course on the question of Vitamin D milks which are reinforced, both the source and the unitage are declared, I wouldn't have any objection to declaring the source, whether it was concentrate extracted from natural sources, produced by irradiation, or activation, or other means, I don't think anybody would object to that, you want the consumer fully informed in the interest of honesty and fair-dealing.

Q. There is at present some amount of Vitamin D appearing in flour?

A. Very slight, very slight, you might have the equivalent of, I wouldn't want to try to attempt to guess, 426 but I quoted the figures from Coffin, that 258 servings of bread is equivalent to half a teaspoonful of cod liver oil, that is approximately 150 or 160 U.S.P. units.

Q. In the product made fortified with Vitamin D is anything added in addition except wheat flour carrier, so far as you know?

A. So far as I know there is not.

Q. Then you wouldn't know of any way to suggest how to get it in durum flour, and whole wheat flour, and those other products?

A. You can spray it on, you can put it in a emullsifier and spread it on, you could add it in the form of irradiated yeast, that is not a big problem, that is a problem any good chemist can work out in an hour or so.

Q. But it doesn't have to have a carrier, necessarily?

A. Oh, not necessarily, it is preferrable, I think it is, the technique would be a little better if you added it with a carrier, rather than an oil. That all depends upon your conditions, and how much your product is activated, and a lot of things which would have to be determined by probably the production manager, and the chemist or whoever it was, those are plant problems.

Q. Is there any loss of vitamin D after the addition
427 to the flour before it is merchandized?

A. Vitamin D is one of the most stable vitamins we know of. You can subject vitamin D to heat up to 450 degrees, and up to 550 I have personally carried out experiments in adding vitamin D to cooking, and you can heat it up to 550 degrees, and it retains its vitamin D potency for 30 minutes, and that is pretty drastic treatment. They put vitamin D in evaporated milk and drive off 60 per cent of water, and that is done in a vacuum pan and they put it in a can and sterilize it to 215 degrees and still the vitamin potency is retained.

I will cite any number of experiments to show that vitamin D is one of the most stable of the vitamins today.

Q. In so far as heat is concerned, or how about in the presence of calcium phosphate, and bicarbonate of soda?

A. Yes, vitamin D is just natural to be with calcium, because that is one of the things that it acts on, and I would say that that would have no effect on it, and of course you get conditions of high acidity, high alkalinity, and of course you destroy that but you destroy any biological product or property then.

Q. Do you have any information, then, with respect to the action of vitamin D in the presence of bromate,
428 potassium bromate added to flour?

A. Well, I would say that that would not hurt it a bit unless it was pretty concentrated, if you are referring to what they have been talking here the last few days, that wouldn't hurt it any.

Q. Do you have any figures or any experimenation at all?

A. I haven't any figures but just common sense tells me that.

Q. There is no tendency whatsoever for the concentrates to lose their force, in the solution?

A. Their potency?

Q. Yes, sir.

A. Well, no, I would say no, but we generally figure this way, if you have a concentrate of vitamin D it is a biological product, and except when transferring or shipping it we recommend it to be kept cold, we think that that is—we don't have any evidence that they deteriorate we have tested the stability of these things over years of time and we find that they maintain their strength in vitamin D, but we still recommend that they be kept cold, because

it is still a biological product and you just are never sure what is going to happen in high concentration, because if you have an oil and there is a tendency for the oil to be a little old and a little rancid, you have oxidation and
429 the reaction of other chemicals which you would not have if it is cold, so we just take that precaution like we would a concentrate of vitamin B or C or anything, just keep it cold, because after all you are dealing with a biological preparation.

Q. I take it that you can't give us any recommended minimum amounts of vitamin D in the products other than flour and farina?

A. Sure I can give you a recommendation of a minimum standard or anything.

Q. I mean based upon experience or something of that kind?

A. Based upon experience and judgment.

Q. Well, you may put those in the record, if you can.

A. Subject to—I feel that a lot of these things are going to be clarified.

Q. Under their different headings, if you are going to be here all of that time we can put them in.

A. When the standards for vitamin come out, but I would set the standards as a minimum for any flour as 200 units per pound, even 300, the better judgment of whoever writes the order dictates, 300 would be all right with me, and for farina, I think the figure I quoted, I don't recall what it was, I think 200 units per ounce.

430 Q. What does it run in Sunfed flour, if you can tell us?

A. 380 units per pound.

Q. And in the farina?

A. 400 units per ounce.

Mr. Goodrich: No further questions.

Mr. Campbell: I have no questions.

DR. FRANK L. GUNDERSON, was called as a witness for and on behalf of the industry, and having been first duly sworn, was examined and testified as follows:

Direct Examination by Mr. Campbell.

Q. Will you please state your name, address, and
431 occupation?

A. My name is Frank L. Gunderson. I live in Wilmette, Illinois, and I represent the Quaker Oats Company.

I am a bio-chemist in the Research Department of the Quaker Oats Company, Chicago. My training was obtained at the University of Wisconsin, in the years 1920 to 1929. During that period I took work leading to Bachelor and Master of Science degrees in agriculture with major emphasis on nutritional chemistry, and Ph. D. degree in work now designated as bio-chemistry, formerly known there as agricultural chemistry. My work included also a considerable study of medical physiology.

From 1923 to 1929, I worked also as analytical chemist in the Wisconsin Department of Agriculture.

In 1929, I became bio-chemist of the Quaker Oats Company, to establish and operate a vitamin test and research laboratory. I have continued immediate supervision of all vitamin and other nutritional work. It is part of my regular responsibilities to try to keep abreast of the rapidly increasing knowledge of nutrition, with excellent facilities both in the laboratory and in a nearby public library, direct contact with bio-chemical and clinical research professors who conduct investigations of mutual interest, all help in this.

432 Certain research projects are sponsored by my company in the form of grants in aid or fellowships, and it is my job to be the contact man and meet with the research people on that work.

I attend important nutritional conferences, and act as an editorial associate for the Journal of Food Research. My specialty for fifteen years has been in the field of nutrition, during which time I have published reports in several scientific journals.

I am a member of the American Chemical Society, American Association of Cereal Chemists, and of the Food

and Nutrition Section of the American Public Health Association. In the latter Association I served for several years as a member of the Nutritional Problems Committee on Food Considerations.

Predecessors in this hearing have proposed that certain optional nutritional ingredients be accepted for flour enrichment. If they had not already covered those mineral and vitamin nutritional adjuncts so thoroughly, then I would consider going into detail on those points. I endorse the proposals that the definition of flour be so formulated as to permit reasonable nutritional enrichment with vitamins per se or concentrates thereof, including the following nutritional factors:

Vitamins B-1, B-2, D, nicotinic acid, calcium, and
433 iron.

I now wish to suggest inclusion of Vitamin A, or its precursors and of Vitamin C, ascorbic acid, as further optional ingredients.

For the present the circumstances under which enrichment with Vitamin A or Vitamin C or both can be considered are special rather than ordinary circumstances. I make these proposals in the spirit that in the adoption of a flour definition that the door be not closed to these nutritional substances. I wish to make it clear that within my knowledge these substances as yet have not been extensively used for flour enrichment. Research in the entire vitamin field and in the principle of better applied nutrition is advancing rapidly.

Among the vitamins, these two substances, namely, "A" and "C" are known as being relatively susceptible to oxidative loss or destruction. Research investigators are making such progress that suitable means may well be found to assure the retention of these substances through storage and cookery.

As samples of authoritative—may I emphasize that, purely as samples of authoritative opinion, that significant numbers of people are not obtaining sufficient of these factors "A" and "C" may I offer the following brief
quotations? These quotations are from the book
434 called "The Vitamins" published by the American
Medical Association, in 1939:

Various nutritional authorities throughout the country wrote the respective chapters on invitation by the Medical Association. For Vitamin A I refer to Chapter 5, page

121, by Dr. Lena Booher of the Bureau of Home Economics, U. S. Department of Agriculture. She comments on a survey of diets of families of employed workers made by the U. S. Bureau of Labor Statistics, to quote:

"It is apparent that many members of families in the lower income groups probably are on the border line of a recognizable vitamin deficiency. Because each of these group averages embraces rather wider individual variations in Vitamin A intake, it is to be expected that a fair proportion of persons in the lowest income groups actually receive less than the physiological minimum requirement of Vitamin A. This deduction is amply borne out by other surveys on the incidence of partial night blindness."

And with regard to Vitamin "C"—the third letter of the alphabet, in the same book, Chapter 21, page 407-8, by Dr. Sybil Smith, also of the U. S. Department of Agriculture, I quote:

"When it is considered that in the low cost diets the proportion of ascorbic acid furnished by orange juice 435 was probably much less than in diets of higher cost and that consequently a greater deduction should be made for losses of vitamin before consumption, it will be seen that certainly the lowest cost diet, and probably the next higher except for the farm group, furnished less than a safe allowance of Vitamin "C."

Flour and other foods under discussion this week are comparatively inexpensive among the five or six distinct classes of foods. I am permitted to say that, based on personal discussions during the last few years, with well-qualified officials of the Quartermaster Corps of the United States Army, there is a genuine interest in such possibilities as considered herein.

I therefore propose that the list of optional nutritional ingredients include also Vitamin A or its precursors, and Vitamin C, ascorbic acid.

I recommend that lower and probably upper limits of potency be established to assure judicious exercise of enrichment principles.

The entire question of proper and adequate levels of vitamin in-take is scheduled for discussion at the hearing on Section 403 (J) of the Food, Drugs and Cosmetics Act. I believe that the conclusions drawn from that evidence may determine proper levels for flour enrichment.

436 By Mr. Campbell:

Q. Has Vitamin A another common name?

A. Vitamin A does not have another common name to my knowledge that is of any wide usage, but for this purpose "or its precursors" was used as the phrase to cover carotene and several other pigments which have vitamin A potency. That is to say, that they occur in the plant kingdom and when they are consumed by an animal through some enzymatic action perhaps in the liver, the precurser is converted into Vitamin A, which for all of the world functions for the animals as Vitamin A, per se.

Mr. Campbell: That is all that I have.

Cross-Examination by Mr. Goodrich.

Q. You say that product with these additions is now sold under the name "flour"?

A. I can answer that only to this extent: That a product of flour type with carotene added has come to my attention. I do not know whether it is actually sold nor do I know to what extent—does your question extend to Vitamin C also?

Q. Yes, sir.

A. Insofar as Vitamin C is concerned, I have not seen a commercial product so enriched.

Q. Would you propose that the product be called 437 "enriched flour"?

A. I should rather withhold judgment until after the hearing on 403 (j).

Q. We are looking now for a common and usual name, if that is practicable, under this problem, and if not we need some other name that wil be reasonably descriptive, and can you suggest one of that kind?

A. I think that if there is a product falling in the category of either of these suggestions which I have made, that the name should be descriptive enough to differentiate it from non-enriched flour. I am hoping that action will be such as not to close the door to the use of the word "flour" as a part of the name of the product.

Q. You recognize this as a different product after it has been so enriched?

A. Yes, indeed.

Q. Then the consumer is entitled to know when the enrichment has been added by means other than the increased price?

A. Yes, indeed.

Q. Would the addition of carotene to flour change
appearance?

A. It might probably do so, if enough is added.

Q. Change it to a yellowish color?

A. It might do so, yes.

438 Q. Would the flour, with that addition, change
appearance of another food prepared with that fl
say bread?

A. I suspect that the color would carry right throu
into the baked or otherwise cooked product.

Q. What is the action of Vitamin A, or Vitamin
in connection with bleaching agents, if you know?

A. I don't know of any definite relationship betw
"A" and bleaching agents other than that I would susp
bleaching agents might have a little influence on anyth
which is susceptible to oxidation.

Q. What with respect to the leavening ingredie
added in the form of baking powder?

A. I have no experience on that point.

Q. So far as you know at this time, is it possible
add Vitamin C to foods other than flour, or Vitamin
or A, either one?

A. Why, as a matter of judgment, rather than ac
trial, it is possible to add it; or add them to various fo
but I presume that you probably have some other qu
tion leading beyond that.

Q. I have in mind, what is the necessity of add
them to flours where they are likely to be largely lost
the baking process, I believe that you said, when t
could possibly be added to another product, and
439 tain their potency when they reach the consumer?

A. As I stated in my prepared statement, progr
is quite rapid in this field; and I believe that meth
are now available for stabilizing carotene in certain
flour materials of cereal grain origin. I take no issue w
the inference that other foods might be subject to enr
ment with "A" or "C" and more completely retain th
factors under present and past conditions of effect
enrichment.

442 DR. RUSSELL W. WILDER, was called to the stand as a witness, and having been duly sworn, testified as follows:

Direct Examination.

The Witness: As evidence of my creditability I had better submit my position. I might say that I am Professor and head of the Department of Medicine of the Mayo Foundation, with the Mayo Clinic. Russell W. Wilder is my name.

Secondly, I have the association that I mentioned a minute before, with the National Research Council, as Chairman of the Committee on Medicine, and I am also Chairman of a Subcommittee on Nutrition of the Division of Medical Sciences, National Research Council; and thirdly, my membership on the Food Council of the American Medical Association since 1930.

I wish to bring to your attention certain actions and resolutions of the Council on Foods of the American Medical Association first, and then possibly comment on one or two other points. This Council as you may know consists of scientists and physicians, who serve volun-
443 tarily without remuneration. They are chosen by the officials of the American Medical Association, but after receiving advice, and their procedure is mostly by correspondence, but annual meetings are held, and at those annual meetings for many years Dr. E. M. Nelson of the Food and Drug Administration has been present.

Now, I should like to quote from the minutes of the annual meetings of the Council on Foods, the annual meeting that was held March 7, 1940:

"When the Council was first organized in 1929 there was need for a body of experts to express authoritative group opinion about health claims made in the advertising of food products. The Council devised a seal by which manufacturers could make known that they had accepted the Council's requirements for restriction of advertising claims to those which were considered established. It also has been a requirement of the Council that the nature and amount of each ingredient of processed foods be made known and that there be on labels for such foods a complete declaration of ingredients in the order of their decreasing proportion.

"The new Food, Drug and Cosmetic Act includes provisions for the more precise labeling of processed foods. Definitions and standards of various classes of foods 444 are being developed. No longer are the provisions of the Council regarding declaration of ingredients of compounded foods so necessary, now that governmental agencies are empowered to deal more adequately with this problem. Further, the Federal Trade Commission has had broad powers conferred on it by reason of the Wheeler-Lea Amendment. This agency now has greater authority to police objectionable claims in advertising. There no longer should exist need for detailed examination by the Council of much advertising material, although the demand for the Council of providing an authoritative opinion on questions pertaining to foods and health still remains."

The Council is proposing gradually to change its function from that of supervising the advertising of submitted foods, to the matter of giving consideration to nutritional problems, and obtaining the concensus of opinion of nutritionists on various important food problems to the public health. And one of the problems of that type that the Council has been giving attention to is this matter of the provision of an adequate amount of various vitamins, and this subject of the removal of vitamins from certain foods like white flour, which in the process of the manufacture have had vitamins taken away from them.

445 The interest of the Council on Foods in the matter of the addition of vitamins and minerals to foods dates from a meeting December 9, 1938 of a cooperative committee on vitamins, a committee composed of representatives of the Council on Foods and the Council on Pharmacy and Chemistry, both of the American Medical Association. The following quotations are from the minutes of the meeting of this cooperative committee:

"The idea of fortifying foods with dietary essentials is not new but had its beginning with the introduction of iodized salt * * *."

I am not quoting completely, but I am referring to these, and leaving with you these notes and references to the sources of these quotations, where certain interpretations and meanings which may be interesting for the Administrator to consider can be found.

"As a result of its experience, the Council on Foods in 1936 adopted a statement of general policy regarding this

question. It was then decided that general and indiscriminate fortification of foods with vitamins (as well as minerals) should be discouraged; the Council is aware, of course, that when a need is recognized for a certain dietary essential, and a food is shown to be suitable as a vehicle
446 for that vitamin or mineral, fortification might be justified. New evidence and new problems would necessitate a reconsideration of the problems and policies.

"Among the recent questions presented to the Council on Foods, reviewed by the Cooperative Committee, have been the following:

"What policy should be adopted in regard to the addition of Vitamin B-1 to cereal products? The Council has taken no objection to the addition to cereal products of wheat germ or dried yeast as sources of the vitamin B complex. Various considerations render unpractical the addition of wheat germ or dried yeast to many foods. Synthetic thiamin chloride is now available commercially and it has been suggested that milled cereal products might well have the vitamin B-1 content restored to the B-1 value of whole grain. This question involves many important points which need separate discussion.

"* * * It is becoming apparent that for various reasons, especially lack of knowledge, the people of the United States do not select foods to furnish the best possible diets for the money invested. More data are needed to determine actual intakes, but even with the data now available it is possible to point to some general tendencies toward
447 deficiency in the national dietary."

And then it continues:

"There is increasing evidence, for example, that more vitamin B-1 in the diet may be desirable. Although recent information shows that some meats, a hitherto unexpected source, provide considerable amounts of vitamin B-1, it also has been shown that many whole-grain products of the ready-to-eat cereal class have lost much of the vitamin B-1 which was present in the original form, owning to the heating to which the products are subjected. There may be a need for more vitamin B-1 in the diet, but there is also a need for re-examination of available sources and greater emphasis in educational programs on the need for this vitamin. In any case present progress in teaching the applications of nutritional research to the public is slow because of few agencies devoted to this kind of education.

"The fortification of foods with vitamins (or minerals)

should not be viewed as a substitute for educational programs. Rather it should be considered that fortified foods simply afford an additional source of important dietary essentials needed for the attainment of optimal nutri-
448 tion. Further, if vitamin A is to be made available in the form of fortified foods, such fortification may well be limited to food fats. Similarly, if vitamin B-1 is to be added to foods, those products which naturally furnish this vitamin but have lost it in processing should be the foods selected for its restoration. The addition of vitamin B-1 to milled cereal products thus appears to be justifiable.

"In the opinion of the Council, legislation and regulations pertaining to foods should be enacted with reference to the best interest of the public. Fortification should not be prohibited but it should be controlled."

So far, you see, I have been quoting from the action of the Council, and this opinion doesn't represent mine, it represents that of the Council. But I think it deserves emphasis because it is a point of view that I think worthy of very serious consideration. We don't want to make drugs out of our foods. At the same time, we should not have to go to the drug store for our vitamins.

It is not impossible that subconsciously when we need vitamin A or one of the other fat soluable vitamins, we turn to a fat to get it. I cannot offer proof of that, but it is a suggestion, and that when we subconsciously have a feel-
ing that we want some Vitamin C we don't turn to fat
449 for Vitamin C, we subconsciously ask for an orange or some tomato juice; and likewise when we subconsciously feel the need for any part of the vitamin B complex, particularly for the thiamin of the vitamin B complex, we turn to the cereal grains.

Now, it happens that unfortunately in the process of the improving mechanically the methods of making flour we have succeeded very effectively in removing all of this thiamin from flour, together with a great deal of other valuable nutriant material. But I consider personally that this removal of thiamin, that is the most serious nutritional problem that faces our country today.

In view of these and other recommendations of that cooperative committee, from which I quoted, until I interjected those personal remarks, the Council on Foods at a meeting on March 18, 1939, adopted these resolutions.

"Further consideration was given to the recommendations of the Cooperative Committee on Vitamins, which

have been published recently. After considerable discussion it was decided that mild fortification of cereal products with calcium or iron salts or both might well be recognized. The fortification of cereals with vitamin D was again given consideration and it was decided that such manipulation of cereals could not be recognized because it
did not seem to be in the interest of public health,
450 at least on the basis of present information."

May I stop the quotation there, and insert another personal remark. I am inclined to agree very strongly with what Dr. Scott said earlier this afternoon, about the importance of this problem of osteoporosis in adult human beings. It is very true as he mentioned that we do not have the satisfactory evidence regarding the necessity for Vitamin D in adults that we do have and can provide in the case for children.

But we do see a great deal of osteoporosis in the adult population. It may be due to lack of calcium or lack of vitamin D or both. I am of the opinion that if adult individuals get enough calcium they don't need any more vitamin D than they get out of the sunshine. The observations of these people with osteoporosis indicates that they have not only been deprived of the Vitamin D but they have also been deprived of calcium, and the American dietary is notoriously deficient in calcium, as well as in thiamin; and the absence of calcium rather than the absence of Vitamin D may be responsible for this amount of osteoporosis that we are seeing.

In any case if it is desirable to restore Vitamin D to the American dietary, I still feel inclined to urge that the
place to put it is with the other fat soluable vitamins
451 in the fats, because the place we look for fat soluable
vitamine is in fats and not in the cereals.

To resume then the quotation from this second meeting of the Council on Foods, that is the meeting after that meeting of the Cooperative Committee:

"A further report on the desirability of adding vitamin B-1 to cereal products is being prepared for publication."

And that report was later published by Dr. George C. Cowgill, and the reference to it will be found here, in the Journal of the American Medical Association for December 9, 1939, Vol. 113, pp. 2146-2150.

The case is very strong of the need of extra Vitamin B-1, that is thiamin in the American dietary. As a result of this study that it made of the available evidence the

Council adopted the following statements as a statement of its present policy:

"The Council on Foods desires to encourage the restorative addition of vitamins or minerals or other dietary essentials, in such amounts as will raise the content of vitamin or mineral or other dietary essential of general purpose foods to recognized high natural levels; with the provision that such additions are to be limited to vitamins or minerals or other dietary essentials, for which a
452 wider distribution is considered by the Council to be in the interest of the public health.

"The Council is opposed to the indiscriminate fortification of general purpose foods with vitamins or minerals or other dietary essentials. By fortification is meant the addition to a food of such an amount of a vitamin or other dietary essential as to make the total content larger than that contained in any natural (unprocessed) food of its class.

"The following fortifications are recognized by the Council as being in the interest of the public health: (1) the addition of vitamin D to milk to an extent not to exceed 400 units per quart, no objection being made when the added vitamin is obtained from a natural source, if it carries with it one or more other vitamins; (2) the addition of vitamin A to substitutes for butter to an extent not to exceed the amount of vitamin A in butter of high natural content of vitamin A, no objection being made when the added vitamin is obtained from a natural source, if it carries with it one or more other vitamins; (3) the addition of iodine to table salt in an amount not to exceed one part of sodium or potassium iodine for each 5,000 parts of salt; (4) the addition of calcium salts to wheat flour or other cereal
453 product in an amount such that the calcium content of the finished product does not exceed 0.075 Gm. of each 100 calories * * *"

That is an arbitrary figure about ten times as high as the amount of calcium in whole wheat, but it was felt by the Council that there was justification for considering some means of adding to the American dietary more calcium than it contained, and there is no better source of calcium than wheat flour, no better basic food could be thought of than white flour. Of course, milk is the ideal place to turn for calcium, but many people do not drink milk, and people who do not drink milk are deficient in calcium.

"and (5) the addition of iron to wheat flour or other cereal product in an amount such that the iron content of the finished product does not exceed 0.0015 Gm. (1.5 mg) for each 100 calories."

That is about the amount in whole wheat.

Now, the following quotation is from the minutes of a still later meeting of the Council:

"There has been published in the 1939 report of the Council a statement of general policy adopted by the Council with regard to the fortification or restoration of foods
with vitamins, minerals, and other dietary essentials.
454 As far as general purpose foods are concerned, it was decided that, with few exceptions, fortification of these products could well be restricted to the restorative addition of important nutritional essentials for which a greater intake is considered to be in the interest of public health. In this way processed foods would be brought up to the original high nutritive level of unprocessed foods. A number of specific problems have been presented for the Council's consideration in connection with this rational process of improving the nutritive quality of foods. Breakfast cereal products are usually divided into two classes, the ready-to-eat variety and those which are eaten after cooking. The cereal product having the highest vitamin B-1 content appears to be oatmeal, which may provide as much as 300 International units of vitamin B-1 to each hundred grams of dry material. Whole wheat contains on the average about 165 International units of vitamin B-1 per hundred grams. Most breakfast cereal foods contain considerable less vitamin B-1 than either whole wheat or oatmeal. It was decided that the addition to breakfast cereals of vitamin B-1, in the form of thiamine hyrdrochloride, up to the level of oatmeal, would be in agreement with the Council's previously declared policy.
455 This permits the restorative addition of vitamin B-1 to these products so that they may contain up to 300 units of vitamin B-1 per hundred grams, or 80 units per hundred calories.

"While whole grain cereal products are usually considered to be of nutritional value because of the vitamin B-1 (and iron) which they contain, they also provide calories, protein and certain other members of the vitamin B complex. It was decided that no objection would be taken to the restorative addition of substances rich in riboflavin to processed cereal foods. Claims must be restricted to

statements of fact, however, such as 'this product has been enriched with riboflavin to the value of whole wheat,' or the like, because the principal dietary sources of riboflavin are milk and meats, and not cereals, even of the whole grain variety.

"The foregoing decisions refer to general purpose foods, which means foods which are ordinarily considered to be useful for any member of a family."

From the quotations given above, taken from the minutes of the Council on Foods, it will appear that that Council endorses the addition of thiamine to white flour in amounts ranging from a lower limit of the content of thiamine in whole wheat to an upper limit of the content of thiamine in oatmeal.

456 The content of thiamine in whole wheat varies, as judged by analysis made by Booher and Hartzler, chemists of the Foods and Nutrition Division, Bureau of Home Economics, from a low of 118 International Units per 100 grams for soft wheat to a high of 175 International Units per 100 grams for hard wheat.

Now, I also think that you ought to have introduced into the evidence, into your evidence here, as evidence of the interest of nutritionists in the restoration of flour of the nutritional properties removed from it in its processing, action of the Scientific Food Division or Commission of England, as reported to the House of Commons in 1940, July 18th, by the Parliamentary Secretary to the Ministry of Food. This was announced in the English scientific weekly "Nature," Vol. 146, pages 117 to 118, July 27, 1940. This English program, which I understand now has been adopted, involves adding to white straight flour 50 International Units of crystalline thiamine chloride per 100 grams. This will raise the thiamine content of the English flour from 30 to 80 International Units per 100 grams.

And then lastly, I should like to mention a recommendation recently made to the Food Committee of the Munitions Board of the Army and Navy by the Subcommittee on Nutrition of the National Research Council. The 457 members of this subcommittee, on which I am serving as Chairman, are Doctors McLester, Spies, Dwight Wilbur, Jolliffe and Sydenstricker. All are recognized authorities on nutrition. They, after giving this matter consideration, felt that the Army should purchase flour that was restored in thiamine up to a level that would

represent approximately a low average level for whole wheat, and therefore they recommended that an additional specification be introduced in the purchase of army flour, that it shall contain not less than 40 International Units of thiamine per ounce. This would represent 133 International Units per 100 grams. Whether that recommendation will be followed will depend upon how practical it is to follow it, and the decision, of course, will be in the hands not of this committee, but of those in the Munitions Board who have the purchase of flour for the Army and Navy in their hands.

I wish to emphasize that nutritionists are not satisfied that the addition of thiamine alone makes white flour as good a food as whole wheat. However, in my opinion this single addition would represent a marked step forward in the interest of the public health. As other vitamin factors of the wheat become available and as methods for analyzing flour for their content are developed, they too should properly be added. The point is that restora-
458 tion of thiamine is today a feasible procedure, a standard thiamine content for white flour could be specified and conformance to it could be enforced. Simple chemical procedures are available for analyzing flours for their content of thiamine. A case almost as strong can be made today for addition to flour of riboflavin, calcium and iron, and it is not unlikely that in the relatively near future that other constituents of the vitamin B complex similarly could be considered as suitable for addition to flour.

And so in view of these considerations, I had in mind recommending, as a personal individual, a consumer, that your authority consider the following recommendations:

1. That in formulating definitions and standards of identity of white flour and other derivatives of wheat and other grains, no obstruction be created to procedure which will improve the nutritive properties of such products, but

2. That additions of vitamins or minerals be limited to additions which by decision of the Surgeon General of the United States Public Health Service are clearly in the interest of the public health. It may be that some other authority of the government should be substituted for that suggestion, that matter is not in my province to decide,
459 but it occurred to me that he is a man who would be interested in public health.

3. That additions should be permitted only in amounts judged to be of nutritional significance by the Surgeon General of the United States Public Health Service.

4. That additions should only be permitted when methods of analysis are available by means of which the amount of vitamin or other mineral added to the product can be controlled.

460 Mr. Campbell: I have just one question.

By Mr. Campbell:

Q. You spoke of various constituents of the vitamin B complex. Is that vitamin B complex a term that includes vitamin B_1 within it, with some other constituents?

A. Yes, sir. Originally, in the early investigation of this group of vitamins, it was thought they were all one vitamin, and it was called vitamin B. Then it was found there were different vitamins, and now they speak of the vitamin B complex, and speak of not only thiamin (vitamin B_1) and riboflavin (vitamin B_2), but a dozen other recognized factors in the vitamin B complex, such as vitamin B_6, and nicotinic acid and pantothenic acid and several others that have significance undoubtedly in nutrition, but may be less important than vitamin B_1.

The absence of vitamin B_1, thiamin, leads to very definite mental symptoms and to early development of fatigue.

The absence of vitamin B_2 quite early leads to certain disturbances, particularly of the vision; but it is less debilitating. And the absence of the other constituents has not been studied yet to learn how long it may take to show damage.

461 *Cross-Examination by Mr. Goodrich.*

Q. Do you believe it desirable to fortify flour with Vitamin C?

A. I don't think that is a place to put Vitamin C.

Q. It isn't a natural place for it to be?

A. As I mentioned earlier, I think the subconscious instinct guides us to fruits when we want Vitamin C. The natural place to put Vitamin C would be in canned fruits. As a matter of fact, it has been the opinion of the Council there is relatively little Vitamin C deficiency about, and I believe that was also the conclusion in the Steibeling report, that C was not one of the vitamins found very frequenty lacking.

Q. What is your opinion with respect to the fortification of flour with Vitamin A?

A. I feel that Vitamin A has no place in flour, because I feel again strongly, that Vitamin A being a fat soluble vitamin, a natural place to look for it is in the fats, and we ought to have it in our butter and we ought to get enough of it in our butter and something ought to be done about it, and we ought to get it in our margarine, and I think it is a crime, personally, that margarine should be permitted to be sold without containing Vitamin A. We do need Vitamin A badly, but not in our wheat and wheat products. We need it in butter, and in butter made from cows fed with silo in the winter time, they ought to be fed with Vitamin A, and the margarine ought to be brought up to the level of good June butter. But I don't think we want it in our wheat products.

462

Q. In your opinion would the addition of .1 of 1 per cent of wheat germ oil to flour—and I believe that is a hundred grams of flour—be of any nutritional value?

A. I haven't sufficient evidence to say that it would. Until very recently, it was the opinion even of the father of Vitamin E, Dr. Herbert Evans, out in California, that it had no place in the human metabolism. That opinion was based on the fact it was thought this vitamin had principally to do with fertility.

Very recently, within the last couple of years, there has been presented some clinical evidence that certain muscular weakness could be benefited, that certain definite pathological abnormalities of the muscles were benefited by treatment with Vitamin E. I still don't believe that those conditions can be related to deficiency of Vitamin E. If they are benefited by it, I rather think it is because of a therapeutic effect from this vitamin. You know, one can use vitamins and hormones, either as restoratives or something missing, or give them the way you give a drug. The best example of that would be thymosis, which you give in minute doses to a person who has lost his thyroid gland, and bring him back to normal. And we also use Vitamin E in large doses in certain specific conditions we want to treat that way. So I think this Vitamin E may be of value as reported, given in large doses for these muscular abnormalities, but one can't deduce from that the abnormality resulted from a lack of the Vitamin E. I, personally, don't believe the evidence to date indicates Vitamin E has a definite role in human nutrition.

463

Q. That would be the only purpose for adding wheat germ oil from the nutritional standpoint?

A. I still would object to its being added to flour or wheat products, because of the fact that, like the Vitamin A and Vitamin D, it is a fatty soluble vitamin, and I think we would naturally turn to a fat for it.

Q. What is your opinion as to the effect of the addition of small amounts of potassium bromate to plain flour?

A. I have no opinion about that. I imagine the amount used is small enough so that it is not likely to produce bromatism. Some people are sensitive of bromides
464 and it produces a breaking out of the skin, a rash; I suppose the amounts added to flour are so small that one need not consider that.

Q. Does potassium bromate have chronic toxicity, as far as you know?

A. Yes, it does. It has toxicity if given in a large enough amount. It accumulates and ultimately brings on a breaking out of the skin which may be pretty serious. But I don't know what dose would be necessary to effect that. I have only seen it, for instance, in cases that were being treated with fairly large doses of bromides so as to produce a sedative effect. I don't think small doses would do it, any more than small doses of iodine added to salt have ever been shown to cause any iodism.

Q. Doctor, should there be a definition and standard identity adopted for an enriched or a fortified, or a restored flour, as it has been referred to during the course of the day?

A. That is a question to which I have given a good deal of thought and I have never been entirely satisfied with. To call it simply a restored wheat flour is perhaps not right, because that implies you have restored everything taken away.

I have thought of "wheat flour with restorative
465 additions" as a possible name for it; but that is too long a name. So it is extraordinarily difficult to label this thing, and while I think it is a very important thing, yet I think it is a very important thing to label properly. If I happen to think of something better, I will be glad to communicate with you.

Q. What is your opinion on "enriched flour"? Have you given that name any thought?

A. I heard that name mentioned earlier and like it fairly well, except that it implies you have added some-

thing more than was originally present in the wheat. If somebody should take ten dollars out of your pocket and give you back five, you wouldn't hardly say you had been enriched.

Q. What would you say about the name "special dietary flour"?

A. Well, I wouldn't like that, for the reason that it is my hope that by some means or other we can, before very long, educate everybody concerned to the place where all of us will be able to buy no other kind of flour than flour restored as much as feasible to the situation or condition of the whole wheat. And we don't want to eat health foods, those of us who are already healthy.

467 Q. Doctor, on this addition of potassium salts, excepted from your opposition to the indiscriminate fortification of foods, what particularly did the Committee consider in that category? Monocalcium phosphate, and what else?

A. Well, the Committee didn't officially or in writing in its minutes express any preference for any salt. I am sure there was some discussion of the question of the desirability of using calcium carbonate as opposed to calcium phosphate, because the physicists generally have an idea that a certain relation between the intake is desirable, and the phosphate intake is already high in comparison with the carbonate, and, therefore, it would be advantageous, in attempting to balance it, to use carbonate rather than sulphate.

468 Q. What is your personal opinion as to what calcium salt should be permitted, if you have one?

A. Well, I wouldn't be too insistent on that score. These milling people have a lot of technical problems which have to be met, and as long as there is no serious public health problem involved, and I don't really believe there would be in using calcium phosphates, I should insist on it.

From the theoretical point of view, it might be advantageous to use calcium carbonate, but that would be only from the theoretical point of view and I don't believe it would make a great deal of difference.

Q. In what form should the iron be added to cereal products?

A. There, again, I don't remember whether any expression of opinion occurred at the meetings of the Council. As far as I, myself, am concerned, I am a little too hazy about my iron physiology to want to answer that

question without looking it up. There is some que
about the relative absorbability and the utilizabilit
feric as opposed to ferous iron, and I have forgotten
what it is.

Mr. Goodrich: I have no further questions.

Redirect Examination by Mr. Haley.

469 Q. Doctor, do I understand you propose to let
human animal depend on instinct to select a prop
balanced diet as far as fats and the minerals are
cerned?

A. That is a very smart question because we all rec
nize that the human animal instincts have undergone v
serious deterioration and one of the reasons we want
put thiamin back into flour is so as to make it impos
for the human animals with their poor instincts to
getting thiamin, and the same would apply to calciu

Still, I think most of us will agree, won't we, that
do not want just to indiscriminately use flour for
purpose of dumping all the things we have to get for
nutrition, and that the idea of making any one food
all-purpose food, and making any one food a comp
food, when we do have an opportunity, after all, of go
out and eating meat and butter as well as bread,
getting our milk as well as the fruit; there are cert
classes of food and it seems to me reasonable and rati
able to stick to this general principle that if we have
instincts worth while—and I think there are still so
instincts preserved in some of us—that we would use t
instinct in turning to the fruits and to the fats for
appropriate vitamins, and for these Vitamin B substan
particularly thiamin, to the cereal foods.

470 Of course, thiamin occurs in other foods. It
fairly rich in the pork, in the meats, peas and bea
But the amount of meat one eats in a day doesn't sup
enough unless it is pork, to make up for the fact that
get so much of our food in the form of sugar and wh
flour which has been deprived of its thiamin.

Therefore, without restoring our white flour, or st
ping the consumption of sugar, which I don't suppose
possible, I don't suppose we can possibly hope to do tha
we are going to be shy on thiamin.

Q. Hasn't it been the policy, or, rather, the expres
opinion of the Committee on Foods of the American Me

cal Association, that any restoration or fortification of vitamins, if there is a problem at all, should be properly confined to two or three basic foods names, like flour and milk and cereals?

A. That has been a guiding motive, if it has not been expressed in writing, and I am not sure it has not gone into the minutes. It is felt, and it is certainly my personal feeling, that the way to approach this business of improving the American Dietary was through staple foods. Of course, the Council on Foods has been concerned with this attempt to improve the standard of advertising, and the foods we have had submitted to us, for the most part,
471 have been unstaple foods, have been not staple foods, but have been processed foods, breakfast foods of one kind or another, and most of our time has been taken up with such foods.

The proposal I would like to make to somebody who had the authority, would be that all flour be restored as completely as it is feasible and practicable to restore it and then your breakfast cereal manufacturer would not have to worry about adding any thiamin because it would be there originally.

Q. Don't put too much burden on the flour manufacturer. We are only asking for a little.

By Mr. Gunderson:

Q. With regard to suitable food fortification under the Council Opinions, that 750 milligrams of Ca might be added per 100 grams of cereal foods; and then, furthermore, after hearing your comment on that, I think it would be helpful to us to hear you elaborate a little on, let us say, the reasoning back of that.

How did you reach such a figure?

And, frankly, I am pleased with the fact that you have included that as an exception, and I would like to hear a little more about it.

A. The clause reads:

"The addition of calcium salts to wheat flour or other cereal products in an amount such that the calcium
472 contents of the finished product does not exceed .075 grams for each 100 calories,"—

and that would be 75 milligrams for each 100 calories, or, in the case of flour, it would represent about 300 milligrams or .3 of a gram for each 100 grams—3½ ounces.

It was a suggestion of Dr. Cowgill, as I remember, that

that figure be used on the assumption that nothing more than flour could be expected to provide more than 200 grams, that that would be a half, that the flour thereby would carry about half of the calcium requirement of the day. The average flour consumption is assumed to be about 6 ounces a day, and on the basis of its containing .3 of a gram of calcium, that would represent about half of the estimate of calcium per day. I think that reason was what led him to that particular figure.

Mr. Gunderson: Thank you.

By Mr. Vandenover:

Q. How would that compare, Doctor, with the original amount of calcium that would be contained in the wheat?

A. I think that is about ten times the amount of calcium in the original wheat, the average of it, at least. I think I mentioned before that these were exceptions to the principle of restoration as opposed to fortification that had been recognized by the Council, and that this was clearly and admittedly a fortification, as opposed to a re-
473 storation.

By Miss Van Horn:

Q. Is there any indication that calcium added to the flour is utilized physiologically, or is that just a chemical application?

Would it be utilized in wheat as well as the calcium in milk, for instance?

A. That is a subject some of you people can perhaps advise about with more authority than I can. I think Dr. Cowgill feels that is true, and I believe that in Wisconsin, at the Agricultural Department, they found no matter what form they fed the calcium, they got about the same form of utilization. I think it can be given, in almost any form and be absorbed. Even calcium oxide has been utilized. I have some personal experience in calcium experimentation and I know the absorption does not proceed as rapidly when you use a less soluble calcium salt when you use a soluble salt. But where it is a matter of absorbing only a small amount of calcium, that one can get, for instance, a satisfactory absorption with tribasic calcium phosphate as he can with calcium carbonate or with dibasic calcium phosphate.

Presiding Officer Willcox: Are there any further questions of this witness?

(No response.)

474 I guess that is all.

(Witness excused.)

Is Mrs. Hader here?

Mrs. Hader wants to testify as a consumer and states she could not be here after today. Unless there is an objection, I will ask her to take the stand now.

Mr. Goodrich: May we take a short recess before we start on this? I understand it will take about a half hour.

May we have about a five minute recess?

Presiding Officer Willcox: All right.

(A short recess.)

We will continue the hearing now.

Whereupon:

MRS. JOHN J. HADER, appeared as a witness on behalf of the National Consumers League, and, being first duly sworn by the Presiding Officer, was examined, and testified as follows:

Direct Examination.

Presiding Officer Willcox: Will you state for the record your name and representation, please?

The Witness: My name is Mrs. John J. Hader. I represent the National Consumers League. I am now a home maker, living in Springfield, Virginia. I have just a very brief statement to make.

475 I believe that the proposed definition and standard of identity for wheat flour is in the interest of the consumer. In regard to the use of potassium bromate as an optional ingredient, I am convinced from scientific evidence that the consumer would hardly be properly protected if its use is now permitted.

The tendency to use chemicals in food manufacturing as a substitute for skills, experience and careful supervision, is so strong nowadays, that the Government should lean backwards in making sure that no harm can possibly be done to the health of consumers.

The proposals to add Vitamin B_1 to flour also requires close scrutiny. In spite of much scientific progress, there is still uncertainty as regards the value of adding vitamins to every-day foods, and rather than let a flour with added Vitamin B be sold indiscriminately to the public, it might be wise for the present to consider it as a special dietary

food. There is danger of advertising exploitation of flour containing Vitamin B_1.

During this last decade, as wheat flour has become steadily more refined, we have heard nothing from advertisers about the wonderful substances which were gradually being eliminated from flour. I fear that if Vitamin B_1 and other substances present in whole wheat are added to wheat flour for general consumption, we shall wit-
476 ness a tremendous advertising campaign about the marvelous effects of these elements, which will make people over-confident about the value of these products and cause them to forget that whole wheat flour is still the only complete flour.

Commercial exploitation may also persuade people to pay too much for a substance that can be had without extra cost in the whole wheat.

Vitamin D flour should likewise be regarded as a special dietary food, and when you buy vitamin perparations in drug stores, a special dosage is usually commended and if Vitamin D is added to several foods, there can be no control over the quantities consumed.

Finally, I would like to mention that if Vitamins A, C and D are added to flour, it is actually changing the identity of the product, since these vitamins are not present in any appreciable quantity in whole wheat.

That is all I have to say, and might I ask that the relevant parts of it might be incorporated under the testimony as to the other different types of flour?

Presiding Officer Willcox: Is there any objection to that request?

(No response.)

I think it might be proper, then.

Do you want to cross-examine, Mr. Goodrich?

477 Mr. Goodrich: No, only to point out—

Cross-Examination by Mr. Goodrich.

Q. Whom do you represent, please?

A. The National Consumers League.

Q. And explain, for the record, what that association is?

A. That is an association of people who believe in improving living and working conditions of industrial workers. It has been active for a number of years, and

was very active in working for the original Food & Drugs Act.

Mr. Goodrich: I think that is all.

479 DR. REGINALD C. SHERWOOD, was presented as a witness on behalf of the industry, and being first duly sworn by the Presiding Officer, was examined and testified as follows:

Direct Examination by Mr. Thode.

Q. Dr. Sherwood, will you please state your name, residence, and occupation?

A. My name is Reginald C. Sherwood. I reside in St. Paul, Minnesota. I am employed as a chemist by General Mills, Inc., Minneapolis.

Q. What is your present capacity with the General Mills, Inc.?

A. I am General Manager of the Research Laboratories and Vice President of the Research Products Division of General Mills.

Q. Will you state briefly the educational background and the experience of the last 25 years that would qualify you to discuss this subject?

A. I have been trained as a chemist and first pursued courses of study at South Dakota State College, leading to the degree of Bachelor of Science in 1914; Master of Science in 1916.

480 Later I took graduate work at the University of Minnesota, where in 1925 I was graduated with the degree of Doctor of Philosophy, with a major in agricultural chemistry.

I have been employed as a chemist in various capacities, first at the South Dakota Experimental Station, and later in regulatory work with the Food and Drug Division, Montana State Board of Health, and later as an Assistant Professor in Chemistry at the Montana State College; then as Instructor and later Assistant Professor in the University of Minnesota.

For a period of five years I was Director of the Minnesota State Experimental Flour Mill, and for the past ten years I have been employed in research by General Mills.

and in recent years I have been engaged a fair part of the time in researches relating to retention and addition of vitamins, minerals and other nutritive factors in food products.

Q. Have you written and published any material on this general subject?

A. Yes, I have published on the subject of flour milling and baking and related subjects, in cereal chemistry, a series of bulletins as Director of the Minnesota State Experimental Flour Mill.

Q. Are you a member of any societies or organizations interested in this kind of work?

481 A. Yes, member of the American Chemical Society, member of the American Association of Cereal Chemists, members of the American Association for Advancement of Science, and the Institute of Food Technology.

Q. Directing your attention to the proposed definitions appearing in the August 3, 1940 issue of the Federal Register, do you believe there now exists a basis for associating in flour many of these so-called optional ingredients and these nutritive elements we have been discussing?

A. Yes, sir, I do believe there is such a basis.

Q. What is that basis?

A. There is a sound nutritional basis for it. Whole wheat has long been recognized as a good source of certain factors, and its place has been well established in the dietary for generations. It has been recognized for a long time that in the refinement of flour made from whole wheat that not all of the nutritive factors are retained in refining the flour.

There seems to be an increased interest on the part of nutritionists in providing as much of these nutritive factors in wheat flour as can be so incorporated.

Consequently, a number of mills have experimented in producing types of flour which retain many of the desirable baking properties of refined products and at the same
482 time have incorporated in them nutritive properties equal to or approaching whole wheat, in so far as that is practicable. And since these types of flour differ widely from white flour, in their chemical and nutritive composition and differ widely from whole wheat flour in their baking properties, it seems as though there exists a substantial basis for a consideration of a different type of definition and standard for flours which have these

particular properties and which don't logically fall under either of these classes.

Q. Will you proceed in your own words, Doctor, to give us the circumstances which you believe support the suggested association of these elements in white flour?

A. As a basis for this discussion, I would like to refer first rather briefly to the nutritive value of wheat and certain of its milled products. Next I shall mention the need for more adequate nutrition, especially in the low income groups, citing a few typical statements from the literature to show the views of prominent nutritionists.

Third, I want to describe, then, the existing commercial situation with reference to production of certain types of wheat flour containing vitamins and minerals and show how these wheat flours can contribute to better nutrition.

483 Wheat is one of the basic foods of civilized man. In the United States alone some 100,000 barrels of flour are consumed annually. This corresponds to an average consumption of more than 150 pounds of flour each year by every man, woman and child. In terms of daily consumption this is roughly 6½ ounces or 650 calories, of food energy. Nutritional authorities have estimated that the consumption of wheat products supplies one-quarter to one-third of the energy requirements of the American population.

Such an important item of the public dietary merits careful examination, particularly from the standpoint of its nutritive value. As science has progressed, the number of available facts has increased, and in the light of modern knowledge such an examination can be made much more intelligently than would have been possible a decade ago.

Most of this recent enlightenment has come in the fields of vitamins and minerals, particularly the former. Scarcely thirty years have passed since the first vitamin was discovered and the existence of this word in our vocabulary has been of even shorter duration. In this brief period of time, however, much has been learned, and today it is recognized that even with adequate food supplies life
484 would be impossible unless vitamins accompanied the consumption of food.

Not only are vitamins important qualitatively but also quantitatively, since clinical evidence has demonstrated

that unless the amounts consumed are adequate, life is maintained at the expense of poor health.

Of the several vitamins known to be necessary for man, wheat contains A, B-1, G, E, and the pellagra-preventative factor nicotinic acid.

Information regarding the necessity for Vitamin E is rather scanty, but it has been shown to be necessary for lower animals.

There is some evidence that wheat also contains vitamins B-6 and pantothenic acid, but the facts are far from complete and not much is known of their role in human nutrition. Of the above-named vitamins, vitamin A is found in wheat in such small amounts that this grain is not an important contributory source.

Vitamin B-1, or thiamin, however, is of extreme importance, since wheat is an excellent source. The amount varies from 1.2 to 2.4 U. S. P. units per gram (equivalent to 35 to 70 units per ounce) depending upon the type and variety. Most bread wheats range between 1.45 and 1.75 units per gram (about 40 to 50 units per ounce) and the daily consumption of the amount of B-1 found in 6 485 ounces of whole wheat would supply the entire minimum requirements of the average adult (assuming an adult needs 250 units daily, the amount which I believe is cited in the Federal Register of September 5).

Vitamin G, also called B-2 and riboflavin (preferably the latter in the newer nomenclature) in the amount found in whole wheat is apparently of less nutritional significance than vitamin B-1. Wheat contains 1.75 to 2.65 micrograms of riboflavin per gram or 50 to 75 micrograms per ounce; 6 ounces of wheat will supply about one-third the present accepted minimum daily adult need (assuming 1.5 milligrams per day is required as cited by McCollum). This is, however, a very substantial contribution for a singel article of common food.

There are no published data on the quantitative occurrence of vitamin E in wheat. Wheat germ contains an appreciable amount and to a lesser extent wheat bran is also a source of this vitamin. Future studies may reveal that significant amounts exist in other tissues of the wheat berry. The uncertainty which surrounds our knowledge of the quantities of vitamin E in wheat is equally present in our knowledge of its role in nutrition. Some animals require vitamin E and there is limited evidence of its

benefits to humans but nothing is known of the latter's dietary requirements. Accordingly, the nutritional
486 merits of wheat with regard to this vitamin can not yet be evaluated.

There is practically no evidence concerning the quantity of nicotinic acid, the pellagra-preventative factor, in whole wheat. It is well-known, however, that wheat germ is a source of this vitamin, as germ has been used successfully as a dietary remedy in cases of pellagra. The need for nicotinic acid in human nutrition is well established by the experience with pellagra.

From this brief outline it can be seen that wheat is of major nutritional importance, not only for its protein and high energy value, but also because it can contribute to the diet appreciable quantities of the food accessories, particularly vitamins B-1 and G. It is probable that as more knowledge is gained, other vitamins naturally present in wheat will also attain significance.

In addition to vitamins, wheat also contains important minerals. There are calcium, phosphorus and iron. Of these three, iron is perhaps of most importance since the amount present is high in relation to many other foods. Some nutritional authorities have advocated a greater general consumption of whole wheat products primarily for increasing the dietary supply of iron. Wheat contains approximately 0.005 per cent of this element and the inclusion of 6 ounces in the daily food suppiy would furnish more than half of the 15 milligram average daily
487 requirement.

The quantity of phosphorus in wheat is also appreciable, but the small amount of calcium is less than needed to balance the phosphorus. Optimum nutrition requires approximately 1:1 ratio of calcium and phosphorus since they function cooperatively in metabolic processes. Because of the unbalanced ratio in wheat, some authorities have advocated the addition of calcium to wheat products. The recent legislative action in England which requires the "restoration" of all wheat flour included calcium as one of the ingredients to be added.

Only a small portion of the wheat consumed as food in this country is actually present in the human dietary as the whole grain. It is estimated that more than 95 per cent of human consumption of wheat products is in the form of white flour. Accordingly, any practical evaluation

of wheat for its nutritional service to man must be based on wheat flour rather than on whole wheat. This has been done by many investigators interested in public food supplies. Because of the recognized superior nutritive value of the whole grain, nutritionists and others have recommended the more wide-spread use of whole wheat flour. In spite of these recommendations the consumption of whole wheat flour has not materially increased. Recently in-
488 terest has developed in new types of wheat flours containing the important nutritive factors of the natural grain.

Q. Just a minute, Doctor. Can you tell us right there what the estimated consumption of whole wheat flour is? What percentage of flour?

A. According to the information available to me, not more than 2 or 3 per cent of the total flour milled is represented by whole wheat flour.

At this point I want to quote the published statements of serveral authorities. In the interest of brevity the quotations will be short, but citations to the complete published papers or books will be given.

First I would like to quote from Dr. Lydia J. Roberts from the symposium of the American Institute of Nutrition at Toronto, April 26, 1939. Her paper is published in the Journal of Nutrition, Volume 17, the proceedings, page 22, 1939.

I would like to state, parenthetically, that I will probably find it necessary to indulge in some repetition, as several other witnesses preceding me have referred to the same articles. However, it seems necessary to complete the story by referring to the same articles.

Mr. Goodrich: Just go right ahead.

The Witness (reading):

489 "Available evidence indicates that the diets of many American people are deficient in calcium, Vitamin B_1, and the pellagra-preventative factor as well as in other dietary factors. The ideal method of effecting improvement would seem to be to increase the use of protective foods and to return to some extent to a larger use of less highly milled cereals and other refined foods."

A quotation from Dr. Russell M. Wilder, whom you have just been fortunate enough to hear on the stand. This is taken from the Northwestern Miller and American Baker, July 5, 1939, page 52.

"Fortification based on the principle of insuring the

quality of food should be encouraged. The benefits to the public health to be obtained by the addition to staple foods of vitamins and minerals, if fully enforced by government regulations, would match that heretofore achieved in the field of sanitation."

Another excerpt from the same paper:

"Above all other foods, flour is the food that the poor depend on mostly. If flour were fortified merely enough to restore to it the vitamin B_1 content of the whole wheat, the entire bakery group of edibles would be converted over night from products nutritionally poor in this vitamin 490 to products rated as excellent."

I would like to quote also from Dr. George R. Cowgill, and this is a brief quotation from a fairly long article by Dr. Cowgill in the Journal of the American Medical Association, Volume 113, page 2146, December, 1939. I am quoting merely a paragraph from his summary:

"There are grounds for believing that American dietaries as a whole are unsatisfactory with respect to the content of vitamin B_1. The examination of available food statistics as well as of recently collected American dietaries, the observations of clinicians concerning the high therapeutic value of vitamin B_1 in conditions hitherto not suspected to be due to lack of this factor, and the observations of the value of added vitamin B_1 to the dietaries of many children all support this belief. It is believed that prosecution of a program fostering addition of vitamin B_1 to staple American foods according to the principles discussed in the present report would be definitely in the interests of the public."

And now a quotation from the report of the Cooperative Committee on Vitamins of the Council on Foods of the American Medical Association, Vol. 113, page 595, of August, 1939, quoting:

491 "On the basis of the foregoing discussion, the Cooperative Committee adopted the following resolutions regarding future policies for consideration by the Council on Foods:

(1) Resolved that the restorative addition of vitamins or minerals, in such amounts as will raise the vitamin o mineral contents of foods to recognized high natural levels, be encouraged; with the provision that such additions are to be limited to vitamins or minerals for which a wider distribution is considered to be in the interest of public health, and with the further provision that the additions

are made only to foods which naturally are principal sources of supply of the vitamins or minerals in question."

Quoting again from the Council on Foods:

"The Council on Foods desires to encourage the restorative addition of vitamins and minerals or other dietary essentials, in such amounts as will raise the content of vitamin or mineral or other dietary essential of general purpose foods, to recognized high natural levels."

Then a statement quoted from the American Journal of Public Health, Volume 29, page 792, 1939:

492 "There is another way in which our national nutrition might be improved. If manufacturers and processors of various staple foods would develop methods to retain or restore the natural vitamins and minerals that are sometimes removed from these foods, their popularity and abundance in the diet would assure a greater intake of essential food factors.

"Wheat and other grain products are outstanding examples. In the refining of flour, much of the original mineral and vitamin content is reduced. Some of these substances, but not all, are restored when white bread is made with milk solids, as is not the usual custom in the baking industry. White bread is our best and cheapest source of necessary food-energy, and there is no reason why it should not now be liberally used in a well balanced daily diet, but it would be even more valuable if it contained a larger quota of the Vitamin B-1 (thiamin) and the iron of the unrefined wheat flour. The same can be said of milled white rice, another common cereal."

I would like to quote also from Drs. Stiebeling and Phipard, from U. S. D. A. Circular No. 507, published in January, 1939, where on page 56 they state:

"The diets of approximately three-quarters of 493 southern white families furnished 15 milligrams or more of iron, but half of the North Atlantic diets fall short of this quantity. * * * Flours and cereals made varying contributions depending on the proportion of lightly milled varieties selected."

By Mr. Thode:

Q. That is United States Department of Agriculture, is it?

A. Yes.

Another quotation from the same circular:

"There is probably little danger of serious vitamin B-1 deficiencies if individuals regularly select a goodly share

of their needed calories from foods that have not been artificially refined or depleted of their vitamin B-1 by the processes of preparation."

That quotation is included to indicate that in their belief these naturally unrefined or undepleted foods are desirable. As I shall show at a little later point, we have not made adequate progress in educating the public to eat the unnatural whole wheat grain. Therefore it seems desirable to take a different approach to this problem and try and supply adequate vitamins in other types of wheat flours which are not too highly refined.

Another quotation from Stiebeling and Phipard, Circular 507, page 82:

494 "The experience of physicians that vitamin B-1 therapy is frequently useful in alleviating gastro-intestinal disorders and certain neuritides may be associated with the fact that diets of about a tenth of the families furnished less than 300 International Units of vitamin B-1 and about half or less than, 500 International Units."

Again on page 82 in the same circular:

"The widespread incidence of pellagra in the South is evidence of serious deficiencies in the pellagra-preventative factors in diets of low-income groups in that section of the United States."

And still another quotation from the same circular:

"Freer us of grain products especially in their less highly refined forms in place of part of the refined sugars and fats, would also contribute to the enrichment of diets in important nutrients, especially iron and vitamin B-1."

495 I would like to read also a quotation from Mary Swartz Rose, her book entitled "The Foundations of Nutrition," published in 1938. This is in further reference to iron, quoting:

"Of the mineral elements lost in the manufacture of white flour, iron is the one that can be least well spared. In 92 dietaries analyzed by Sherman cereals contributed one fourth of the total iron. Since the less the money available for food the more dependence there will be on the cereal foods, those yielding iron should be regularly chosen, as they can be made the carriers of this essential element with little or no extra cost. Studies of Children's dietaries make it quite evident that no very economical diet for a child can be liberally supplied with iron with-

out the use of cereal foods (including the breadstuffs) which contain it."

Again from the same book, on page 404, quoting:

"The cereal foods as a class are primarily sources of energy, valuable for their abundance, economy, ease of digestion, and bland flavor. Since they can be eaten freely by all, they become significant as sources of protein although it is not of such quality or quantity as to permit of their being relied upon as the sole source. When
496 those preparations are selected which include the germ and the bran, the cereal foods, including bread, may make important contributions to the mineral content of the diet (especially iron) and also the vitamin B content."

Quoting again from the same book, on page 507:

"To follow the rule of a quart of milk for each child and a pint for each adult will mean that about one fourth of the total calories will come from this one item. In a moderately priced dietary another fourth, at least, should come from the cereal grains and among foods of this class selection should be made in such a way that at least one half of the calories carry iron and vitamin B."

Now I wish to quote from Dr. McCollum's book, "The Newer Knowledge of Nutrition," the 5th edition, 1939, page 471:

"It has been frequently pointed out during the past twenty-five years that, as a nation, we are eating too large a proportion of our nutrients in the form of refined and manufactured products. This practice constitutes a new experience for the race, and there are numerous records which demonstrate that western dietaries are frequently of poor quality in respect to several nutrients, among them thiamin."

497 And the single sentence from another point in his book:

"* * * In such cases the remedy is not a source of thiamin alone but a better food supply."

A number of these quotations have been introduced to show these nutritionists recognize the necessity for certain of these vitamins and minerals, particularly iron and vitamin B_1. And as I have pointed out and will continue to emphasize, wheat products can supply in a substantial measure these particular nutrients that the nutritionists are calling to the attention of the public.

Quoting again from Dr. McCollum:

"Riboflavin is an important factor actuating cell combustion processes as the oxidation of sugars. It also complements the iron-containing respiration enzyme. • • • Evidence indicates that riboflavin is not synthesized by the animal cell; consequently it must be supplied by the diet."

I would like to introduce one quotation from a publication by the United States Department of Agriculture, Yearbook Separate No. 1668, entitled "Human Nutrition." This is a reprint of Part 1 of the Yearbook of Agriculture for 1939. From page 327, quoting:

"Flours, meals, and other grain products have always formed a large part of the food supply in most parts of the Temperate Zones throughout the world. The 498 grains are easily and cheaply grown; they are cheap to distribute, since they occupy relatively little volume in proportion to food value; and they are comparatively easily protected against deterioration. They are especially important in low cost diets because they are cheap sources of several nutritive values—calories, proteins, and iron. The less highly the grain is milled or refined, the more it contributes in minerals and vitamins, particularly in iron and vitamin B_1."

These several quotations, of which I have given only a few of the huge number available, have been introduced at this time to indicate the fact that wheat is generally accepted as a nutritious food or product with particular reference to vitamin B_1 and it is an important source of vitamin B_2 or riboflavin, and an excellent source of iron. I wish to introduce them to support some of the statements I make.

I have stated that wheat is of major nutritional importance. Whole wheat is recognized as an excellent source of vitamin B_1 and iron, and a good source of vitamin G, but relatively poor source of calcium. The vitamins and minerals are not uniformly distributed throughout the kernal but are concentrated in certain tissues while other tissues contain only small amounts. The outer layers 499 and germ are high in these factors, and the endosperm is low.

White flours comprised almost entirely of endosperm contain only 10 per cent to 20 per cent as much B_1 and 20 per cent to 25 per cent as much G as whole wheat.

Mr. Goodrich: What were those figures on riboflavin?

The Witness: Twenty to 25 per cent as much G as whole wheat. Of the total quantity of vitamin B_1 in wheat, straight grade flour contains about 15 per cent, germ about 15 per cent, and the low grade flours, bran and other by-products combined about 70 per cent.

Recent research made possible by new rapid assay methods has revealed that a portion of this 70 per cent of the total thiamin in wheat can be returned to bread flours by the proper selection and blending of mill streams. Thus wheat flours can be milled containing as much B_1 or thiamin as the whole grain, but containing much less fiber and ash than whole grain, and possessing baking properties far superior to whole wheat flour.

While the vitamin B_1 content of this type of flour can be raised to whole wheat level by such a milling method, the accompanying increases in vitamin G, calcium and iron are not as great. Other suitable sources of these three dietary essentials can be added in relatively minute amounts, however, so that the finished flour will be equivalent to the whole grain in the four important factors, namely, B_1, G, iron and calcium.

The program of producing staple food products containing the important nutritive factors in amounts present in the natural raw materials from which the products are derived is being called "restoration" by the Council on Foods of the American Medical Association, and by others. Wheat flour prepared in the manner just described is popularly termed "restored wheat flour." In this process of making restored flour, wheat is the sole source of vitamin B_1, and a contributory source of vitamin G, iron and calcium. It is also possible to make restored flour in another way.

With the recent advent of methods for making vitamins B_1 and G (or thiamin and riboflavin, respectively) by synthesis, and for making highly potent concentrates from natural sources, the materials are now available for adding these dietary essentials to white flour, thereby raising the B_1 and G content to whole grain levels. Compounds of calcium and of iron can also be added to attain whole grain levels. The amounts required of minerals, pure vitamins or their potent concentrates are very small. Bread made with such restored flour can be distinguished from ordinarily bread only by chemical or biological tests.

In making either type of restored flour—

By Mr. Thode:

Q. Just a minute, Doctor. I would like for my own information to get the significance of that sentence. You say it can be distinguished. You mean visibly, do you?

A. I mean from the standpoint of appearance and flavor it cannot readily be distinguished from the ordinary type of white bread we are accustomed to.

Q. But it has in it, also, in addition to the usual bread contents, these additional elements?

A. That is right, in the amounts to which they are added to raise the bread to the nutritive level of whole wheat bread, in respect to iron, calcium, thiamin and riboflavin; but only by chemical or biological tests can the presence of these vitamins and minerals be proven.

Q. The baking action would be the same?

A. The baking action would be the same as in normal white flour.

In making either type of restored flour, nicotinic acid (the pellagra-preventive factor) and other vitamins or minerals natural to wheat may also be added, if desired.

Thus there are at least two ways of meeting the 502 numerous requests for more nourishing wheat flours.

It is of interest to learn the recent action of the English Parliament requiring millers to add vitamin B_1 or thiamin and a calcium salt to white flour. These ingredients will be introduced into the flour stream at the mill. In a short article entitled "Reinforced white flour" in the July 27, 1940, issue of "Nature," Dr. T. Moran and Professor J. C. Drummond have discussed the program. I want to quote a few short excepts.

"Dietary surveys have established that the nation as a whole is not receiving sufficient B_1."

Q. That is what nation? The English nation?

A. The English nation. I am quoting from this English publication. Quoting again from another section:

"The proposed supplement to white flour should therefore, greatly reduce B_1 deficiency."

Both of those quotations refer to the English situation. Calcium is being added to make the ratio between this element and phosphorus more favorable to maximum utilization in human metabolism.

Therefore it will be noted it has been recognized by the English that thiamin and calcium are both needed and they have decided a convenient means of supplying these is to require their incorporation in flour at the mill. Perhaps I

might comment that the situation is somewhat dif-
503 ferent from that in which we find ourselves. The English government has required millers to add to the wheat flour, while here we are in a hearing where millers are requesting the privilege of adding these extra nutritive factors and asking that the government give them that privilege of so incorporating these nutritive factors.

The addition of vitamin B_1 to flour is a sound and economical means of introducing the vitamin into the diet. B_1 is heat labile, and is readily extracted from foods which are cooked in boiling water. Thus large losses of B_1 may occur preparing many foods for the table. In contrast to this, the baking of bread leaves more than 90 per cent of the vitamin unimpaired and in its physiologically active form.

That is one of the reasons why flour and bread can make a very material contribution to the vitamin B_1 content of our dietaries.

Riboflavin is not easily destroyed in cooking most foods, but some losses will occur as this vitamin is all soluble in water. The vitamin G of flour is transferred to bread, however, without any measurable loss.

The production of restored wheat flour is past the experimental stage. General Mills has been manufacturing and selling this type of flour for more than three months, following a period of about two years of research in
504 which the process was developed. Certain other milling companies are producing flours reinforced with vitamins and minerals. The production of restored wheat flours is apparently an established commercial practice.

As I have previously mentioned, whole wheat flour constitutes a very small per cent of the total flour consumed. This small quantity has been fairly constant for at least a generation. The federal standards have long recognized whole wheat flour, and in the proposed definition and standard of identity, whole wheat flour is defined.

The new type of special nutritive flour is being called "restored wheat flour." It is less highly refined than white flour; it contains the whole wheat level of vitamin B_1, B_2 and the minerals calcium and iron; but it conforms neither to white flour nor to whole wheat flour under the newly proposed definitions. This restored flour differs materially from whole wheat in ash content, color and baking properties. When the baking properties of the restored flour, whole wheat flour, and a straight grade

flour are compared, it is found that the restored flour is much closer to the straight grade than the whole wheat type.

Since nutritionists have stressed the public need for restoration of important vitamins and minerals to white flour, suitable sources of certain vitamins and minerals are available, and the milling industry has demonstrated that restored wheat flours can be produced commercially containing the whole wheat level of thiamin, riboflavin, calcium and iron, it appears to be in the best interests of the consumer for the government to promulgate a definition and standard of identity for a new type of flour such as that described here as "restored wheat flour."

Q. Doctor, if you were to propose a new definition for a product such as you have described, in what respects would the definition differ, should it differ, from the proposed definition for wheat flour or plain flour?

A. The principal way in which it would differ from the proposed definition for wheat flour would be in the requirement that the flour would contain essentially the whole wheat levels of these four nutritive elements which I have been discussing, namely, thiamin, riboflavin, iron and calcium. I would suggest that that be a requirement in the definition in order that this new type of flour would be at least equal to whole wheat flour in those particulars.

There would be some other differences. The ash content might be somewhat higher than white flour, depending upon the method by which it is made. As I have already pointed out, there is more than one way of making such a flour. A large part of the contributions of vitamins and minerals can be obtained from mill streams. They can be supplemented then by other sources, or, if that is not desired, the miller may use an ordinary grade of white flour, patent grade, straight grade flour, and make a larger supplement by putting in pure thiamin, pure riboflavin, concentrates of those two products, and compounds of calcium and iron.

The ash specifications, the color of the flour, and some of the physical characteristics would naturally be somewhat different if the flour were made in the two different ways. That gives considerable latitude to the milling industry in making this type of flour.

Q. In what other respects would it differ? What would you conceive would be the vitamin and mineral content,

and the optional ingredients and the amounts used, and so forth?

A. I think there should be a requirement that the amount of these four nutrients should be set at a definite level. I don't see how the regulatory department could police such a product without having numerical values, and I am prepared to suggest some values for consideration by the Foods Standards Committee. The values I would suggest are those that seem to be reasonably close to whole wheat levels, based on available information, and I
507 thing those numerical values should be written into the definition so that all flour produced under this definition and so labelled would conform to the minimum values set up.

Q. Taking the four items that you suggested—vitamin B_1 (thiamin), vitamin B_2 (riboflavin), iron and calcium, will you suggest for the record the minimum requirements which you believe are justified with your understanding of the content of whole wheat.

A. Yes. I will suggest for consideration a minimum value of thiamin of 1.4 International units per gram, which is equivalent to 40 International units per ounce.

Q. It is my understanding that that figure which you are suggesting represents approximately the average vitamin B_1 content of the grades of wheat lowest in B_1 content.

A. Well, that value, as near as I can determine, represents somewhat less than the average of breadwheat. It comes closer to the average of soft wheats. It does not represent the minimum value of all wheats which we have examined, because it does not seem desirable to set a figure as low as that. Neither does it represent a value so high that it would be unattainable easily in manufacturing operations. It seems to me to be a reasonable value—

Q. If you will excuse me. My question was directed as to whether it represents the average of the lowest
508 grades of wheat. Is that correct, the average, about, of that figure?

A. As I cited earlier in my discussion, we find whole wheat runs as low as 1.25 in certain types and as high as 1.75 to two units. This represents somewhat less than the arithmetic mean of the values we have obtained and I am suggesting a value slightly lower than that, because I believe as a regulatory value it should have a value which would not be an unreasonable limit.

Q. What about riboflavin?

A. For riboflavin I have suggested a minimum standard of 2.0 micrograms per gram. That is equivalent to 56 micrograms per ounce.

Mr. Goodrich: Give that again, if you will.

The Witness: For riboflavin, 2.0 micrograms per gram of flour. That is equivalent to 56 micrograms per ounce.

It is more difficult to arrive at a satisfactory minimum standard for riboflavin, I think, than for thiamin as there is less published information concerning the riboflavin content of wheats. In our experience this represents a value just a little less than the average value of the better grades of whole wheats. And it seems a reasonable value to suggest for consideration by the Standards Committee.

509 By Mr. Thode:

Q. How about calcium?

A. Calcium, I am suggesting a minimum value of .04 per cent, calculated as the element Ca. That is very close to the average value of whole wheat as we find it. There are reports in the literature that whole wheat contains from .03 to .05 per cent. We find that a number of samples have shown in the range of .04 and .045. This seems to be a reasonable figure to suggest.

Q. Then you have iron as another suggestion?

A. We have a suggestion for iron as another required nutritive factor, and for that I am suggesting .004 per cent, calculated as the element as Fe. The basis for that is the number of iron determinations we have made of whole wheat in which we find that iron varies from .0035 to .0045. Therefore it seems reasonable to suggest a value of .004 per cent.

Q. Would you propose that a flour having such required ingredients also be permitted to have any optional ingredients?

A. Yes, I think it would be highly desirable to include optional ingredients as well as the required ingredients, and I would suggest the following optional ingredients:

1. Nicotinic acid and/or nicotinic acid amide;

510 2. Pantothenic acid;

3. Vitamin B_6;

4. Vitamin E;

5. Compounds of phosphorous.

Q. Of the suggested required ingredients, is there positive means of making determinations to police and control the suggested limits in each case?

A. Yes, there are means. There are biological means

for determining them, and there are also more rapid methods, either chemical or chemical and biological methods combined for determining those two vitamins. The rapid methods are being pretty well established, particularly the ones for thiamin. There has been less work done on the methods for riboflavin. They are being studied continually, however, and are being much improved, and some of those methods seem to be entirely satisfactory for the control of such a product. There are well known standard methods for determining calcium and iron.

Q. In your opinion, would there be anything restrictive or prohibitive which would impose upon any portion of the milling industry that desired to qualify and to make such a flour? In other words, are the ingredients and in the amounts you are suggesting there, available, either in the mill stream or in the open market in an easy sort of way?

511 A. Yes, I am sure they are available to everyone. As I have described, a portion of the vitamin B_1 and G can be obtained from mill streams. If it is not desired to make the flour with the use of mill streams, or concentrates of thiamin or riboflavin, the pure products can be obtained. In some cases there are several companies supplying such products and they should be easily available to everyone. There are compounds of calcium and iron also standard commodities and available to anyone who wishes to buy them.

Q. You pointed out when you described the proposed flour that you might suggest an ash limitation a little higher than the white flour definition. For the purpose of illustrating the difference, let us take the proposed ash determination or the method of determination suggested in the white flour definition, one twentieth of the protein plus .3. Would you suggest a definite figure for this type of flour?

A. Yes, I will suggest something. I don't know whether it is the correct figure, but I am perfectly willing to suggest one. I think it ought to be a little bit higher than the level set for white flour.

Q. Why?

A. And if the same basis of calculation were used,
512 namely, one twentieth of the protein plus an added factor, if that factor were .5 instead of .3, that would allow a net increase of .2 per cent in the ash in this new

standard, that is, an increase above the level suggested for white flour.

This seems to be necessary, as one of the objectives in making this type of flour, is the attainment of the whole wheat level of calcium and iron. Obviously if you are going to raise the level of the calcium and iron, we are going to introduce mineral compounds, since it is the mineral compounds in the flour which form the substance we describe and report as ash. If we are raising those mineral contents, we will raise the ash content of the flour.

Part of the minerals would be obtained in the mill streams, selected in the process of the milling; but part would be added, also, if we are going to reach the whole wheat levels in the form of compounds of the calcium and iron. In this connection it should be noted that certain portions of the wheat kernal, which I have mentioned here as mill streams, are rich in vitamins and also are rich in these mineral elements. And when we select mill streams to raise the nutritive level of wheat flour, we are selecting at the same time some of the mineral elements. For-
513 tunately that is true. We can contribute added vitamins and added minerals at the same time by making the selection from the streams. Otherwise we would have to depend solely upon outside sources of minerals. And since both of these are desired, the easier the system of supplying them, the better the milling practice.

Q. This suggested increase in the ash would be in relation to the increased nutritive mineral elements you would be introducing?

A. Yes, that is the sole purpose of raising the ash limit. If we are attempting to make a flour equivalent to whole wheat flour in these mineral essentials, calcium and iron, we must select those two elements either from mill streams or from compounds that can be added during the process of milling. And obviously when we do that, we are raising the ash content, and to permit a convenient manufacturing operation, it seems desirable to raise the level above the limit that has been suggested for white flour.

The limit doesn't have to be raised as high as whole wheat flour, because it has been demonstrated already in actual manufacturing operations that the level of calcium and iron can be raised to whole wheat levels of those two elements without attaining the ash content of whole wheat. So it seems reasonable to set a level which would permit

the production of flour under this type, namely, restored
514 wheat flour, with an ash content in the range of 1.0, 1.1 or possible 1.2, and that final ash content, of course, would be influenced by the protein content, if the method proposed by the government is used for setting the level.

Q. Would you have any objection, if such a definition were promulgated and accepted, to a plain and conspicuous definition of the ingredients? In other words, whould it be acceptable if such a definition were agreed upon, to have the Administrator determine that all of these required ingredients, so-called, or optional ingerdients, permitted in the definition, would have to be declared?

A. Declared on the label?

Q. Declared on the label.

A. I don't know of any objection to declaring them on the label; if they are existing in the product, claims for them would be expected to be made. I see no objection to having them declared on the label. It might simplify the label procedure if the standard were set for a particular name, whether "restored wheat flour" or whatever name is selected, and then under that, according to the procedure followed with other products, it may or it may not be necessary to label them. I should think that would be referred to the discretion of the government as to whether optional ingredients should require a label.

515 Q. Doctor, by suggesting this definition, you are not necessarily taking the position that optional ingredients could not independently be suggested and accepted under the definition of wheat flour?

A. No, I am not suggesting that. I think it would be unfortunate if optional ingredients were not included under the definition for wheat flour. There may be a public demand for certain types of flour, for special uses, which would not include all of these nutritive factors, and the only way those flours could be made would be by having the individual factors cited under optional ingredients. I see no way in which this proposal for a separate definition conflicts with the idea of including optional ingredients under wheat flour.

Q. You have suggested that the definition containing minimum requirement of 40 International units of vitamin B_1 per ounce, as a means of allowing mills that might be grinding wheat low in vitamin B_1 content to qualify. As a matter of actual practice in your process, what do you attempt to attain in a vitamin content?

A. In the flour we are now making, with these four ingredients mentioned, we are attaining a level of 50 to 60 units per ounce, at the present time. We have set for the purpose, for the present, a minimum of 50 units per ounce.

516 Q. Do you believe there is any need for any maximum limitations on any of these required ingredients?

A. Personally, I doubt the necessity of maximum limits. I can't believe that anyone would add huge quantities of vitamins. Vitamins are expensive. There would be no harm in raising the level substantially above the minimum suggested because none of these products is harmful and there would be no serious objection that I can see to setting an upper limit, but I wouldn't see much necessity for it.

Q. But if there is a maximum placed, it should be somewhere in the range of whole wheat?

A. If a maximum is set, I should think it should be set somewhere in the range of whole wheat, but I think it should be substantially above the average value for whole wheat, because we already know wheat varies somewhat in its vitamin B, content. We have examined samples of the wheat which have run as high as 2.0, I believe, units per gram. And if a maximum limit were set at the average level or slightly above, then the manufacturer might find some difficulty in producing the product according to his normal routine, staying under that maximum.

I think if a maximum is suggested or set at all, it should be set two, three or four times above the average level one would expect to attain. That would prevent any-

517 one from indulging in any ridiculous additions in order to sell an unusual product and make extravagant claims for it. Perhaps that precaution should be taken in order to prevent any unscrupulous manufacturer from adding extraordinary amounts.

Q. Doctor, where in your opinion should a suggested definition for this type of flour find its place in the regulations? In what order, in the definitions as promulgated?

A. All I can do is give my opinion on the subject, because I can't anticipate, of course, the government reaction to the order. But this flour as described here corresponds reasonably well to types of white flour in its baking properties. It corresponds fairly close to whole wheat flour in its nutritive properties, at least in so far as these four elements are concerned. Since it has the

physical characteristics and the general appearance and the bread baking properties are not very far from white flour, it seems to me the logical place to appear in a series of definitions would be adjacent to the white flour definition, because for all practical purposes bread baked from it is essentially white bread.

Mr. Thode: If it please the Presiding Officer, I offer here in quintuplet GENERAL MILLS EXHIBIT marked with Roman numeral I, consisting of a proposed defi-
518 nition of what we have called, for lack of a better term, "Restored Wheat Flour." We hold no brief for that term.

522 Appearances: (Filed on September 12, 1940.)

Edna Van Horn, 1404 20th Street, N. W., Washington, D. C., appearing in behalf of the American Home Economics Association.

523 DR. REGINALD C. SHERWOOD, the witness at time of adjournment yesterday, resumed the stand, and was examined, and testified further as follows:

Direct Examination (Continued) by Mr. Thode.

Q. Doctor, I would like to know whether in your opinion, you believe the introduction of such a definition as we discussed yesterday, establishing a new standard of identity for a new type of flour, would serve the purpose of promoting honesty and fair dealing in the interest
524 of consumers?

A. Yes, I believe it would. It attempts to set a standard for certain nutritive properties, below which flours could not be marketed, and I believe that is in the interest of the consumer.

There is no doubt about it that the Milling Industry will be importuned by consumers, nutritionists and bakers to provide such flours, and I think a very logical approach to the control of such flours is to set up a standard which has rather definite values established that all manufacturers must meet.

Q. Is this suggestion completely speculative or anticipatory, or is there at present a flour being made that can conform to that suggested definition?

A. No, it isn't speculative. There is a flour made that conforms with these specifications. It has been produced and sold to bakers and is meeting with a certain measure of acceptance. It has been on the market, the particular one I am referring to, made by General Mills, a comparatively short time. There has not been an opportunity yet to determine the extent to which it may be produced in the next few years, because it takes a reasonable measure of time for bakers to experiment with such a type of flour, to find out whether it fits into their scheme, and then to offer it to the consumer and get some trade accept-
525 ance among the consumers before expanding its use.

But the flour has been produced, not only experimented with, but in commercial lots, and has actually been sold. And I might mention there are other types of flour, somewhat similar to this, that may not have exactly the same specifications, but are quite similar, and which might come under this same definition, or, with slight modifications, might come under this same definition.

It should not be difficult at all for anyone in the milling industry to produce a flour which would meet the specifications. It is merely a matter of setting up the right type of manufacturing procedure.

Q. Are the specifications which we have included in this definition representative at all of the maximum specifications of the flour which you have been discussing as being on the market at the present time?

A. Yes, they are representative. The flour we have been producing has somewhat more Vitamin B_1, B_2, slightly more calcium and iron, than the minimum limit suggested here.

In the manufacture of any product, it is necessary to keep the actual level of such factors reasonably above the minimum suggested, to avoid accidental differences in the content and also to allow for tolerances which occur in all manufacturing processes. That is one reason why
526 any manufacturer must set his limits slightly above the limits of any such definition.

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527 I would just like to get one thing more clear, Doctor.

In proposing this definition, you are not contending, are you, that mills should be denied asking for the privilege of adding specified optional ingredients for special purposes in the white flour definition, are you?

A. No, there is no such intent in proposing this definition. I think the white flour definition should include optional ingredients and give the miller the opportunity to make white flour with these various optional ingredients, one or more, as he chooses, because certainly there will be demands for special types of flour with specific optional ingredients, and I can conceive of a demand for flours for certain areas in the country or for certain types of bread for certain special uses, where it might not be desirable to have all of the ingredients that are included in the proposed definition.

So I think this should not conflict in any way with the white flour definition, and requests for optional ingredients under that should be granted.

547 *Cross-Examination.*

By Mr. Caspari:

Q. Dr. Sherwood, if I am not asking for anything confidential, I wish you would tell us what ingredients you are using in flour now not included in Section 15, and tell us when you started using them so that the record may contain that information.

A. In this particular type of restored wheat flour, that I have been describing, we are using riboflavin, calcium and iron compounds. We have experimented with thiamin, and if we did not acquire the thiamin in mill streams,
548 why, then, of course, we would add thiamin to the flour, in the manufacturing process. Those are the four required nutrients that have been suggested. If nicotinic acid were also included as an optional ingredient and one wished to produce such a flour, obviously he would have to have the nicotinic acid.

Q. Do you remember when you added riboflavin?

A. Remember when we started adding it?

Q. Yes; what year.

A. Yes, commercially in 1940.

Q. How about calcium?

A. The same year.

Q. And iron compounds?

A. The same year, commercial operations.

Q. And is the same true with Vitamin B_1?

A. Yes. It was several months ago when this flour was first put on the market and formally offered for sale. The

experimental work has dated back over some two years or so.

Q. Have you added any of these products to flour prior to 1940, for commercial use?

A. Not for commercial use—experimentally.

Mr. Caspari: That is all.

Cross-Examination by Mr. Gunderson.

Q. I would like to ask with regard to restored
549 flour. It is clear to me, I believe that there could be two possible kinds of flour with two quite distinctive baking properties. Is it your idea that the name of the one type of restored flour would be so designed as to differentiate it from the name of the other type of restored flour?

For example, I am wondering how one would label the restored flour made by the procedure wherein patent flour is lifted in its B_1 content solely by the addition of synthetic B_1. Can you stand on that so that the record will be more clear?

A. Yes. I would like to make clear my ideas on the subject. While I have talked about two methods of making this, I have not considered that there should be two types of flour at all. That is not in the proposal and that is not the intention. I have merely suggested you can approach this in two different ways, that you can get all of the Vitamin B_1 or thiamin you desire in the flour to come to the whole wheat level, from mill streams, or any portion thereof from mill streams, and it is my opinion that there should be a single definition, because the definition should be based upon the nutritive characteristics of the finished product and not based upon the method of production; that
550 the producers should obviously be privileged to approach this problem in any way they wish.

And while I have said there are two methods, I have merely described it that way to show in one way you can get a large amount of the vitamin and part of the mineral requirements, and then another way you can use the shorter extraction flour, the flour we are now calling white flour, and even those with low ash content, and by incorporating concentrates you can obtain the same end.

I think in this production, millers should be allowed enough latitude to go up and down the scale. In other words, to use part of their vitamins and minerals in the mill steams, and part from concentrates they supply, and

adjust these proportions to suit their own demands and the demands of their particular customers.

There is some difference in the baking properties of the flours made in the two ways, of course, because one obtains a longer extraction, with somewhat different baking properties, and a little more flavor, a little different grain and texture, when you use more of the mill streams.

And the miller could have the same privilege of making different types of flour as he now has, under the white flour definition, and, in fact, under the whole wheat definition.

551 There are different types of flour, very similar in baking properties and very similar in degree of fineness, and I would not suggest a definition be so restricted that there would be only one way of making the product. That was not intended at all and I want to be sure that is clear. I just want to show there is more than one way of doing this, and the definition, in my opinion, as I have stated before, should set limits for these nutritive factors in the requirements and the approach to those limits should be made by the miller in the way that fits his manufacturing scheme the best.

Q. From the consumer's point of view, how would the consumer know which type of flour is in the bag?

How would the consumer know it is restored flours?

A. I think if there were flours made with somewhat different baking properties, the consumer would soon learn that, as in the United States the consumers get pretty familiar in a short time with the baking properties of different types of flour they like to use—housewives and bakers alike. And they make their selections not on the basis of the Government definition for wheat flour, but on the basis of the characteristics they know the miller is putting into that flour.

Mr. Gunderson: That answers the question.

* * * * * *

556 Q. If there are regulations requiring the manufacture of only 100 percent white flour, so that there would not be an streams available for acquiring natural B_1 in making the flour with the natural B_1 supply.

A. Well, frankly, I cannot conceive of any such regulation which would require any miller to make a certain grade of flour out of a particular parcel of wheat. I think such regulations would be quite ridiculous. I cannot con-

ceive of anything of the kind. I cannot see a problem there at all.

In making a flour of this kind, it is quite obvious that the miller must use wheat supplies available to him, or blend those wheat supplies or the milled products from them, as he sees best to make such a type of flour. I would oppose vigorously any suggestion that a flour had to be made out of a particular parcel of wheat, and there be any attempt to obtain a certain type of flour, restored wheat flour, nutritive flours, or any other types of flour, out of an individual parcel of wheat.

Q. Well, that was my question.

A. Yes; I can't conceive of any such regulation being imposed.

Cross-Examination by Mr. Strowd.

557 Q. But, Doctor, have you any ideas as to the amount of calcium required by an individual per day, the intake of calcium?

A. Yes; the standard seems to be accepted to be best is 1 gram day. It has been proposed by Sherman. Others have proposed values which vary somewhat from that. That seems to be fairly accepted.

Q. Calcium seems to be one of the outstanding deficiencies, doesn't it, dietary essential?

A. It is a dietary essential; yes. And may be a deficiency of the diet.

Q. And offered more often as a dietary essential?

A. It certainly is one which may well be deficient. It is well recognized as a necessity and we must watch our diet to be sure we get proper amounts of it.

Q. In your recommendation, could you say offhand how much calcium you propose to restore to flour would be contained per pound, let us say?

A. Well, the level proposed here as a minimum is .04 percent and it is assumed that in producing such a flour that probably .05 or .045 would be incorporated in order to stay above the minimum, safely above it. So if you take the value of .05 as an average—

Q. I just made some calculations here roughly in my head, and I would like you to check me on them, if I
558 am wrong, and I estimated it on the basis of average per capital consumption, your intake of calcium through this restored flour would be in the neighborhood of .060707 grams, that is, per 6½ ounces.

Do you think that would be quite right?

A. I didn't check your calculations. That may be correct.

Q. Have you ever figured it on the basis of per capita, on the percentage of the individual's daily requirements, which would be very slight?

A. I didn't calculate it, but it can easily be calculated.

Q. I think it would probably be in the neighborhood of 6 or 7 percent per 1000.

A. I didn't calculate it, but it is much less than the daily requirement.

Q. Suppose we took a flour like yours, restored it containing 6 or 7 percent of the individual's daily requirements, which would be a very small proportion; and I would say it would be probably very little help in the diet. Suppose in contrast to that, you would have a flour fortified with 5 or 6 times the quantity of calcium, selling in competition with you.

If you called a flour "restored flour" there is a name that might be rather intriguing and appealing to the
559 consumer from the standpoint of one of the dietary essentials, that is, a most necessary one, the amount in the restored flour would be insignificant and the amount in a flour that is fortified as far as calcium is concerned, which might have less consumer appeal, would be very superior.

Don't you think that might create an unfair competitive condition that would not accrue to the benefit of the consumer?

A. Well, it is a little hard to answer that last part of your question, whether that would create an unfair competitive situation. I don't know the answer to that.

It is recognized, of course, that the whole wheat level of calcium is not high, nutritionally. In other words, whole wheat is not regarded as a good source of calcium. Most of the cereal grains are not good sources of minerals. Wheat happens to be unusual in being an excellent source of iron, but it is not a good source of calcium.

The objective in this proposal was to bring these several nutritive elements to the whole wheat level. Whether that is the optimum objective, of course, is probably a debatable question. In restoring these four nutrients
I have discussed to the whole wheat level, of course
560 we are not making this restored flour an excellent source of calcium.

Q. For the benefit of the consumer's information, from that standpoint, do you consider that this term "restored flour" will be of material aid in permitting her to decide intelligently?

A. Well, I have no strong case to present at all for the term "restored flour". We have arrived at the use of that term in presenting this testimony, largely because the Council on Foods has talked about restoration and has proposed the use of that term. And since we are trying to bring up this wheat to a whole wheat level in these particulars which seem to be the most important ones in whole wheat, we have used the term "restored flour". I am perfectly agreeable to some other type of term.

Regardless of what term is used in a formal definition, I think any manufacturer still has the opportunity to make claims for the product and describe what the product is and what it will do. Those claims, of course, will be conditioned a great deal by the conclusions reached here next month on dietary foods, because undoubtedly that hearing will have a bearing on this whole broad subject.

Q. Council on Foods' first statement of policy, published some in August, 1939, and they then issued a
561 supplementary report on July 20, 1940, in that report of August, 1939, they did not make a statement of policy, or words to the effect that the addition of calcium to cereal products in quantity was not equal to .075 grams per 100 calories, would be in the public interest?

A. Yes, that is right.

Q. Do you recall something to that effect?

A. Yes, they did.

Q. As I see this, the amount you recommend is about 1/6 or the amount to be added to the restored flour is about 1/6.

A. That is right, between 1/5 and 1/6.

Q. And that .075 per 100 calories reflects quite closely to the formula to be used by the British Empire. Is that not correct?

A. I don't believe I have seen that.

Q. It is .6 grams per 100 ounces of flour.

A. They are going to raise it above the whole wheat level?

Q. About the same amount, you would say about 6 times, something like that, is the way the figure is.

A. I don't recall that.

Q. It is about .6 of a gram in 10 ounces, as I recall it.

Now, I don't want to make myself obnoxious in con-
562 tinuing with this line of questioning, but I would like to ask you this one further question:

In your judgment, is whole wheat flour especially adapted to human nutrition, with respect to the balance of vitamins and minerals contained in it?

563 A. No, I wouldn't say that it is. I don't think any of our natural foods are especially adapted, unless possibly it is mother's milk. I don't think they are especially adapted. I think it merely happens to be fortunate enough for us that we can select certain natural foods which fit into our scheme of living and supply some of the nutritive elements we need. Obviously, the wheat kernal is produced to propagate the wheat plant.

Q. That is right.

A. And the mere fact that it has certain of these vitamins and minerals present in certain proportions does not indicate a proper balance for us. You are quite right.

In setting up a program of this kind, however, there must be some objective and you must have some mark to shoot at. And I think it is reasonable to start out by suggesting that more refined flours can be so prepared, with outside additions, if necessary, to bring them up to the whole wheat level.

One of the reasons it has been approached in that way is that whole wheat has been recognized by nutritionists as a good source of energy, protein and certain vitamins and minerals. It isn't presumed to be a complete food in any reapect, and there are many things in which wheat is lacking. And rather than start it out with a proposal to make a wheat flour which is a balanced food nutritionally,
564 it seemed desirable to set up a proposal for bringing it up to the whole wheat level. Because if you start incorporating other nutritive elements—vitamins and minerals and other dietary essentials that might be desirable—you are going to end up with a product which is no longer flour. That is the reason we approached it in this way, believing it was perfectly logical to raise the level to a better baking flour than whole wheat flour, that is, a more refined flour, to the whole wheat level, in spite of the fact that it isn't claimed that whole wheat is a balanced, nutritional product. In so doing, it seemed desirable to include those vitamins and minerals which are naturally present in the grain.

In the case of calcium, your point is well taken, that

wheat is not an excellent source of calcium and it might be desirable to include more calcium than the minimum wheat level—and I am quite in sympathy with that and I would have no objection to seeing a definition proposed by the government which set the calcium limit a little higher than it is set here, if that system can be worked out. I am in sympathy in seeing somewhat more calcium in it.

As I say now, the ceiling we have set in this proposal is the whole wheat level. If we put in more calcium we stray from this restorative program and indulge in
565 fortification, as we have defined those two terms. But from the standpoint of nutrition, there isn't the slightest objection to putting in more calcium, and as to improving the baking properties there is no objection, in addition to and beyond the whole wheat level. That is my personal view on the subject.

Q. Just one more question. You say that wheat is not designed for human nutrition, but the composition is intended for the preservation of wheat for future generations. We have, on the other hand, a statement of policy of representative groups of home economists and nutritionists, setting forth how they believe food should be constructed in order to be of maximum benefit, just as the lumberman saws the tree to fit the house and doesn't build the house to fit the tree.

In view of that fact, I just don't like to take issue with you, but I can't see the particular advantage of having a definition for restored flour, from the standpoint of consumer interest and public welfare. Of course, you can not put out a flour of this type, if you want to. But don't you think that the term "restored flour," used out in the trade, might make a bad competitive situation for somebody who wanted to follow the findings of the doctors and teachers, instead of the accidental composition of the wheat grain?

566 A. I think there is a distinct advantage for the consumer in having a definition for a type of product that has minimum levels for certain of these nutritive factors that are recognized as being important. If such a standard is set, then the consumer will know that all flours so labelled conform at least to those minimum values. Whereas, without such a standard, there may be a thousand different flours with a thousand different values. And I believe that if we are going to put out baking flours with higher nutritive value than some of the shorter extraction

flours, we ought to aim at some definite point. I think that is an advantage for the consumer, to set some minimum levels.

You will note that in this proposal we have made here, we have allowed for optional ingredients, so that some other ingredients natural to whole wheat can be included, even though they were not suggested among the required ingredients. And as I indicated yesterday, and I would like to amplify just briefly a little farther, one of the reasons for writing some of those ingredients in as optional ingredients, particularly nicotinic acid—which is known to be a dietary essential—is that in my opinion there isn't enough information available to show what the whole wheat level is. If it were put among the required ingredients, then we would have to set it at the whole wheat level. But
567 we favor the privilege of nicotinic acid being incorporated in this flour as an optional ingredient. And at a little later time it may be possible with a minimum level for it.

Q. In view of the fact that our knowledge of the composition of the wheat grain is not complete, and our knowledge of nutrition is not complete, a restored flour such as you suggest is really not a restored flour after all, is it?

A. Well, a restored flour as suggested here is not necessarily equivalent to whole wheat in every particular. But the objective here is to select those nutritive factors contained in whole wheat and which are known to be essential, and direct our efforts toward producing a flour of that type. And then after we acquire more information respecting less well known factors in whole wheat, it may be necessary to ask for amendment to include those factors.

I have suggested some of those factors in the optional ingredients. According to the best information, whole wheat contains pantothenic acid, vitamin B_6; we know it contains vitamin E. We know less about the nutritive effects of those products and the human demands for them. Consequently it seemed desirable to put those factors in the optional ingredients and allow them to be included
568 later after it seems desirable to so include them. And if we eventually acquire enough knowledge about all the nutritive factors in whole wheat, then it may be possible to produce a flour which we know is equal to whole wheat in all of them.

As it is now, it seems to me that we have selected the important factors about which we have knowledge, and in

making such a flour as I have been describing, using in part mill streams as the source of vitamin B_1, we know we incorporate some of these other factors. We can't declare them; we can't put limits on them, because we don't know much is there. We have no methods for determining some of these factors. We do know, however, we are returning to a short extraction flour numerous factors which are in whole wheat and possibly contribute something to its nutritive value, aside from the vitamin B_1, B_2, calcium and iron. And I don't think we should hesitate to set up a program of this kind and establish a definition for restored wheat flour, simply because we don't know all the nutritive factors in wheat.

We do know certain things. We know four factors. All right, let us go part way. Let us set up a flour for those four or five factors—if you want to include nicotinic acid as the fifth factor we do know about. And as we make further progress in later years, we can modify the
569 definition.

Mr. Strowd: Thank you, Doctor; that is all I have.

570. *Cross-Examination by Mr. Goodrich.*

Q. Doctor, we understand your company is committed to a policy of restoration of the flour, as distinguished from fortification?

A. Yes; at the present time we are making a flour which we are calling a restored flour.

Q. I am interested in your statement that when you incorporate a number of optional ingredients which are
571 not normally present in the whole wheat, you will eventually end up with a product which is not flour.

What did you have in mind when you made that statement, sir?

A. I had in mind what probably would be a ridiculous situation, that if people wanted to include all conceivable things with flour, you might end up with something which wasn't flour. I wasn't referring to the optional ingredients suggested here at this hearing. I was thinking of mixing flour with all the other kinds of food products. I perhaps should have made that clearer at the time.

Q. We have on the market dietarian products of which vitamin D is one your company does not use. Have you had any experimentation with that or with any other of the dietary products, in adding them to wheat?

A. Yes.

Q. And what was your conclusion from that experimentation?

A. Yes, we have had experiments within vitamin D, incorporating it in flour experimentally. It is a perfectly satisfactory process from the mechanical standpoint. Vitamin D contributes the nutritive factor for which it is well known, and I see no reason at all why vitamin D should not be included as an optional ingredient. If there is a demand for such a flour, there is no reason it should not be produced.

Don't misunderstand me. That wasn't one of the
572 things I was speaking about being incorporated in this ridiculous flour or diluted product, because such an addition of an optional ingredient is in a very minute quantity and would have no effect upon the baking characteristics of the flour.

Q. Does the vitamin D contribute to the nutritional value of the restored flour?

A. Yes, in direct proportion to the amount you add.

Q. And why did your company exclude that from the flour they put out, if you can answer that.

A. Simply because the program suggested by the Council on Foods included at the present time vitamin B_1, B_2, calcium and iron; and so we started out with that program.

Q. Pursuant to your policy of restoration only?

A. Yes, sir, and not because we have any objections to Vitamin D as a vitamin.

* * * * *

587 Q. What name is given to this special flour now required to be made under the British system, if you know? I believe you called it "reinforced flour" yesterday.

A. I don't recall whether a name has been proposed. Let me refer to this article in "Nature" that I quoted. The title of the article is "Reinforced Wheat Flour," but I have no reason to believe that that is a name set by any legal or regulatory part of their government. I assume this is the title of the article, and I don't recall a name for the product; I don't recall a statement in here as to an exact name. Perhaps Doctor Nelson or someone else in your Department here knows.

Q. Your company has manufactured this special product to cure deficiencies in diet?

A. Well, the purpose of this is to supply flour
388 which has certain well known and recognized nutritive value found in whole wheat.

Q. And which was lacking in the American dietary?

A. Yes, for which there is a need in the American dietary; and based upon many statements of nutritionists, there is a need for more of these factors in our dietray, and this seemed a convenient way to supply them in a common food.

Q. You understand that the greatest deficiencies exist in the lower income groups?

A. That is a statement usually made by nutritionists, that such deficiencies are greater there because those persons with more restricted incomes seem to have less opportunity to acquire a greater variety of foods and thereby a more balanced diet.

Q. How do you propose to distribute this product among that class?

A. Well, it would be offered for sale to anyone who wished to buy it. And since cereal foods, particularly flour, constitute a pretty large fraction of the diet of that group, automatically they would be getting an increase in their vitamin content. Of course, advertising could be directed to that end, with the aid of consumer organizations and home economic societies and nutritionists generally, which
would be helpful in educating these people to select
389 such types of flours.

Q. Enumerate, if you can, the ways in which your product differs from white flour, in baking qualities and texture, and so forth.

A. There isn't a great deal of difference in the baking properties. There is no difference from some types of flour which can be made, and little longer extraction flours which still conform with this present definition of flour, taken under the one per cent ash limitation, and this flour would correspond quite closely to certain longer extraction flours that can now be prepared.

Q. The riboflavin and calcium and iron additions make no difference in baking qualities?

A. There are no recognizable effects we can determine from adding any of those ingredients.

Q. What advantage is there in adding the vitamin B_1, or thiamin, by means of incorporation of mill streams high in vitamin B_1, over the addition of a synthetic vitamin B_1, known as thiamin chloride?

A. It is largely a matter of personal preference. There is some advantage, of course, in using some of the foods we have in the mill. We are producing mill products and we use some of our own products in that way. At the same time we carry into the flour part of the riboflavin which we want to have there. We also carry along some of
590 the calcium and iron—some of it.

So while we are acquiring all of the thiamin needed to get to the whole wheat level, we are contributing these other factors also and have to purchase less of them from the outside. But it is a matter of personal preference, I think, in selecting the way in which one wants to make a flour. We can make a flour with a normal patent or straight grade flour, in which these—

Q. Is it personal preference, or considerations of economy?

A. Well, partly considerations of economy in acquiring the thiamin, because our source of thiamin in mill streams is obviously less expensive than the thiamin purchased on the open market.

Q. Did you hear the testimony given yesterday morning, that the incorporation of these mill streams would affect the texture of the flour?

A. Yes, I believe I heard a comment on it.

Q. What is your opinion on that subject, please, sir?

A. Yes, the incorporation of mill streams would affect the texture of the flour. It all depends on how you are making comparisons. If you are comparing this type of flour we are making with a short patent flour, it is quite obvious there is a difference in the color, the grain and tex-
ture. But if you are making a comparison of this type
591 of flour with a longer extraction flour, which happens to have the same characteristics with regard to grain, texture and color, then you would say there is no difference. It depends upon what your standard is, in other words.

It is true that the addition of some of these mill streams gives you a flour which is not identical in baking properties with a short patent flour. That is quite true.

Q. What floor would you set upon the amount of B_1 to be incorporated?

A. One point four U. S. P. units per gram, or 40 units per ounce.

Q. With reference to vitamin B_2, vitamin G, or ribo-

flavin, which I understand are all the same, what amount of that is added?

A. We suggested two micrograms per gram.

Q. Is that substantially what you are adding today?

A. No; that is less than we are now adding. The figure which we are claiming is 30 Sherman Berkwin units per ounce, because we have been using that terminology. That corresponds to 2.6 micrograms per gram.

That, in our opinion, is somewhat above the average whole wheat. But information in the literature and in our own laboratory regarding the whole wheat content of riboflavin is not abundant. There are relatively few determinations compared to the large accumulation of in-
592 formation in respect to some of the other factors; so we have set that level to start with with this flour and have suggested 2.0 as a floor for this flour, because it should not be too difficult to make that and keep these within the range we find whole wheats.

Q. What carrier do you use for the addition of this synthetic product?

A. The riboflavin?

Q. Yes, sir.

A. We are using now a riboflavin concentrate which is produced commercially and which is available.

Q. By the Commercial Solvents Company?

A. Produced by the Commercial Solvents Corporation, yes, sir.

Q. Explain what that is, if you will, if you know.

A. I am not entirely familiar with their process, because I have never visited their plant.

Q. It is in liquid form, or is it?

A. No, a dry product, produced by a biological process from natural products, and an extract made subsequently, dried and delivered to us in dry form.

Q. What appearance does it have?

A. Oh, it is either granular or powdered, depending upon what specifications we set for it, and it has a yellowish to light brown color.

593 Q. Then that would affect the appearance of the flour, would it not?

A. With a large amount of it, yes; but in the amounts required it is practically unrecognizable in ordinary baking flour. If you added this to a very short patent, you might see a trace of effect upon color. If you add it to a straight

grade flour, I don't believe anyone can detect it in the finished bread, because the amount added is very small.

Q. How would you define such a vitamin B_2 concentrate for the standard of identity?

A. Well, I don't know just how it could be defined, other than to call it a concentrate of riboflavin from natural sources. It isn't a synthetic concentrate. It isn't made by producing the riboflavin from the elements.

Q. Would you limit the potency of the vitamin B_2 used?

A. You mean the upper limit?

Q. Yes, sir, or the lower, either one—of the concentrate, I mean.

A. The potency of the concentrate. Well, I don't know what limitation ought to be set. I think concentrates of that type should be reasonably potent sources of the material, of course. There is always an advantage in that, and since such a product as this is available, in com-
594 mercial quantities, I wouldn't be surprised if there were other products offered which were substantially less potent. I don't know whether we should set limits for it or not.

Q. What is the potency of the product which you add in your manufacturing?

A. It runs in the range of 4,500 to 5,000 micrograms per gram.

Q. What amount of calcium are you adding?

A. We are adding enough calcium to bring the level to what we have regarded as the whole wheat level.

Q. The figures you gave to Doctor Strowd, I believe?

A. Yes. The analysis of some of our typical examples of flour have shown .045 per cent. We are aiming for a range between .045 and .05 at the present time, in terms of Ca. We think that is slightly above the whole wheat level and we are aiming slightly above it, just so at no time would we be producing a product which is lower.

Q. In what form is it added to the flour?

A. We are adding it now in the form of calcium sulphate.

Q. Do you have any recommendations as to other calcium compounds or combinations?

A. Yes, I think other calcium compounds are acceptable.

595 Q. Such as?

A. Some of the phosphates.

Q. Which of them? Just be specific so that we can have the record clear on it.

A. I think all of the calcium phosphates are acceptable—monocalcium, dicalcium and tricalcium phosphates. They are all acceptable food sources of calcium. They also contribute some phosphorus. We are using a compound which does not contribute phosphorus, since there is a fair amount of phosphorus in the flour anyway.

596 By Mr. Goodrich:

Q. The addition of a product not containing phosphorous would be satisfactory?

A. We find it entirely satisfactory.

Q. Is there a price differential?

A. Not materially, those products are in the same general range of price. I don't have the exact figures in mind but there are several of those calcium compounds that are roughly in the same range.

Q. You don't think that any calcium compound would be suitable, do you, for this purpose?

A. Well, there might be calcium compounds which would not be suitable. There are several which are suitable. I wouldn't want to say that all calcium compounds would be suitable, no. The other radicals might be objectionable.

Q. You believe the promotion of honesty and fair dealing in the interest of consumers requires that we be specific in naming the calcium compounds which can be used for this purpose?

A. I think that that would be all right.

Q. What method of determination do you use in computing the amount of calcium?

A. We use one of the standard methods of determin-
597 ing. The one we are using is the precipitation method followed by titration.

Q. Is that the method of the Association of Official Agricultural Chemists?

A. I believe it is one that is described there or a modification of it.

Q. You would be agreeable to the use of that method of analysis?

A. I suspect so. I would want to review that method and see whether we had found it entirely satisfactory before committing myself definitely, but there are two or three methods for determining calcium. There are some important features in determining the relatively small

amount of calcium here that have to be observed in any method but there would be no difficulty in agreeing to a satisfactory procedure, I am sure.

Q. In what form is the iron or the iron compound?

Mr. Thode: Mr. Goodrich, just a minute. I don't like to interfere in any way; with the desire of helping you, there is a process question and the patentability that is becoming involved in this one issue, and I would prefer if you could ask the question as to what kind of compound of iron might be available or something of that kind to show that there is more than one available but there
598 is a slight question which we prefer not necessarily to have to disclose unless it is proper for you under affidavit form or something of that kind.

By Mr. Goodrich:

Q. In what form could the iron compound be added?

A. There are several different forms in which iron could be added. There are a number of iron compounds that are recognized as satisfactory nutritional sources of iron, such as iron phosphate, iron chloride, chloride is used, there are several iron compounds which I think are acceptable.

Q. Which would you recommend, sir?

A. We have experimented—

Q. All of them, not necessarily confining yourself to the one that you use.

A. We have experimented with three or four of them. The iron phosphate is a compound which has perhaps, if you call it a trade name, it is sold under the name of "saccharated iron oxide" which is an acceptable compound, and chloride would be acceptable, I believe.

Q. There would be some iron compounds which would not be acceptable, I take it?

A. Yes, probably there would be.

Q. Did you cover the amount that you recommend?

A. We suggested the amount of iron on the basis of what we believe is approximately the whole wheat level
599 of iron.

Q. And the method of analysis would be the AOA-C method?

A. I believe so. I am not sure whether that has listed some of these newer methods of analysis for these but again there is no problem that I see on agreeing on a satisfactory method for analysis.

Q. Going now to the other optional ingredients which you have suggested, namely, nicotinic acid or nicotinic acidamide. I can't pronounce that next one—pantothenic acid, vitamin B_6 and vitamin E and compounds of those phospherous elements; you are not using those at this time?

A. We are not adding those deliberately. All of those constituents are undoubtedly present to some degree in the flour, because they are natural constituents of wheat according to the best available information. We know that nicotinic acid is there, and we believe that there is some pantothenic and some vitamin B_6 and so those are all constituents that are natural to the whole grain but we are not adding those deliberately from other sources in the particular flour that we are now making. They were included, however, because they might be considered logical additions and then there might be other manufacturers who wish to add those deliberately and they should have
600 the privilage of doing so, I think.

Q. Regardless of their value in human nutrition?

A. They are valuable in human nutrition. That is why they are included.

Q. Do you have knowledge on each of the subjects?

A. No, not very specific knowledge in human nutrition respecting the rare vitamins. I think it is perfectly clear that nicotinic acid is valuable in nutrition. It has not yet been proven that pantothenic and vitamin B-6 has a definite place in human nutrition but there are experiments which show clinical effects from a lack of those vitamins but I don't think it is well established that those have a definite place in human nutrition. They are suggested for consideration at this time simply because it is believed that they are constituents of natural wheat and if some time later when more information is available concerning the clinical value it may be desirable to have them used as optional ingredients. That is the reason for including them in this suggestion; in the case of phosphorous compounds, of course, they do exist in wheat and they have well recognized value for the element phosphorous that they contain, and I wrote into this proposal, this suggestion of compounds of phosphorous, because some other manufacturers may wish to raise the phosphorous
601 content up to the wheat level, and if so that would give them the privilege. In the case of vitamin E, we

know that that is present in whole wheat. There isn't too much knowledge of its nutritional place in the human dietary. It has been used clinically and experimentally, and it is used in certain special cases beneficially, but we need more information concerning its widespread use, and we are not adding it deliberately. We know it is present in the product we are making because it is present in many wheat products, and it was included there for about the same reason that pantothenic and b-6 were included. The time may come when it is necessary to make deliberate claims for its presence, and that is why it is suggested at this time.

Q. You have qualified, I believe, as a chemist?

A. Yes, sir, I have attempted to.

Q. Is there any way of detecting the presence of one-tenth of one percent of wheat germ oil appearing in flour, added to the mill stream?

A. Well, one could compare the vitamin E potency of the flour without such addition and with such an addition, and you could determine that vitamin E was present if the oil was a potent source of that vitamin. That would not necessarily prove that it came from the wheat germ oil but that would be indicative that that was one
602 source. I haven't given any though to any means of establishing the presence of it. It is a fat or oil which contains constituents common to wheat and wheat flour, and the fat content of wheat flour without such addition is measurable. I don't know how easy it would be.

Q. How long would that small amount last in the process of milling and merchandising of flour?

A. Well—

Q. Considering oxidation there?

A. You mean the vitamin E contained there, the oil would stay there and would be subject to modification the same as any vegetable fat is upon long storage. You are referring specifically to vitamin E that is present in it?

Q. Both, the oil and the vitamin E.

A. Well, that is a question which I don't think anybody can answer categorically. The vitamin E is a very stable vitamin, in wheat germ oil. The wheat germ oil is spread in a thin film throughout the flour and then exposed to oxidation and high temperature and it would be less stable under those conditions, but the conditions of storage would determine very largely the retention of

vitamin E and I don't think that there is an answer to a broad question like that.

603 Q. The position of vitamin E in human nutrition has not been demonstrated at the present time?

A. I don't consider that it has, no, there has been experimental work to that end but I consider it is still in the experimental stage. It has certain recognized effects but its position in human nutrition has not been well established.

Q. Certainly the amount needed in human nutrition has not been touched at this time?

A. No, I don't think it has, and that is one of the reasons that I suggested putting this as an optional ingredient. If it was included as a required ingredient I would not know how much to put in. It has been clearly demonstrated that vitamin E is needed for reproduction of animals, to get it from some source, and it can be assumed on that basis that humans need it, and we undoubtedly get it from some of our foods and we don't know how much we need. It is in the experimental stage, as I see it.

Q. In your recommendation, the statement is made that the required optional nutritive ingredients may be supplied in an amount not exceeding "blank" amount by weight.

What percentage do you suggest?

A. Well, I thought some such provision should be
604 put in there in order to give some limitation. I can suggest the limits within which we have been working and I don't know whether those are the right limits. Perhaps others would want other limits set, and the reason I didn't propose anything definite was because I didn't know what the figures should be. It seemed to me that a ceiling should be set there in order to prevent any ridiculous addition of such products; in the amount in which we are now adding them, riboflavin concentrates, calcium and iron compounds, five-tenths of one per cent would be a satisfactory amount because we are adding much less than that and that would give us an opportunity to shift our sources of supply some and still not interefere with manufacturing operations.

Perhaps it might be desirable to use some other concentrates which would not be so potent and which might be cheaper sources, and perfectly satisfactory from a nutritional standpoint, and in that event assuming that one per cent might be a better figure.

I think it should be agreeable to the milling industry to have such a ceiling figure set, and I see no reason why there should not be.

Q. Do you think it would be advisable to separate the maximum for vitamins and maximum for minerals?

A. Well, I don't know. I suggested this simply
605 to wrap them all up together and set a ceiling limit for the several additions. The sources of calcium and iron that are acceptable for such product are somewhat varied, and the percentage of calcium and iron in these compounds is not uniform. You have a different percentage of calcium in carbonate and sulphates, for example. The objective, of course, is to get a certain level of the element, and in so doing you have to use different sources. I don't know of any serious objection to that, but it was my thought that if a figure was set which still covered these several additions that ought to be acceptable.

Q. The last sentence in your statement, to the effect that any vitamin or mineral added in conformity with this section in the form of a concentrate may be accompanied by any other vitamins and minerals naturally present in the concentrate. Explain that for us, please, sir?

A. Well, there was a purpose in including that, in order to make it clear that if vitamin concentrates such as riboflavin concentrate we are using and possibly thiamin concentrates if they are offered for similar purpose or used, they might carry with them accompanying vitamins for which no claims were made, perhaps, but which could not be removed in commercial operations, and that
606 there should be no restrictions imposed on the use of such a concentrate, simply because it happened to contain other vitamins and minerals than those required and declared in the definition or on the label. That was the purpose for putting that in, just to call attention to that fact.

630 Whereupon

A. M. GILBERT was called as a witness for and on behalf of the industry and having been first duly sworn, was examined and testified as follows:

Direct Examination.

The Witness: My name is A. M. Gilbert. I represent Hecker Products Corporation, and Standard Milling Company.

For the sake of the record we wish to make one brief statement with respect to the use of vitamin B-1, and minerals as optional ingedients in flour. Due to the quality as well as the quantity of evidence already introduced on that subject, it would not serve any useful function for us to develop that line of thought any further. However, we do think that it is relevant and should be considered, that we too, like the other companies, have been adding vitamin B-1 calcium and iron to flour. That has been done for about the past four months.

We call the product flour. We have a brand name which is Vitawhite, but the product itself is flour, and it is a bleached flour.

We add sufficient vitamin B-1 iron and calcium so as to restore to the flour the same amounts of these nutrients
631 as found in whole wheat and we do declare the presence of these ingredients on the label and have a statement that the vitamin B-1 calcium and iron content of this flour is equal to that found in whole wheat.

And in addition to our using those items in this one particular line of flour, it is our plan to definitely increase the use of vitamin B-1 and these minerals in our flours. We feel and think that this vitamin and these minerals should be permitted as optional ingredients in flour in such amounts as will restore to the flour the amounts found in whole wheat.

That is all.

Presiding Officer Willcox: Is there any cross examination.

Cross Examination by Mr. Goodrich.

Q. In what form are you adding vitamin B-1?
A. In the form of thiamin chloride.

Q. What amounts are added at the present time?

A. I can't answer that. I may have someone here who can.

Would you know that, Dr. Sasse?

Dr. Sasse: Four-tenths of a gram in 196 pounds.

Mr. Goodrich: What amount of calcium and in what form is it added?

632 The Witness: I know the forms. The calcium comes by way of dicalcium phosphate and the iron is introduced as iron pyrophosphate.

Dr. Sasse, would you have the amounts of that?

Dr. Sasse: Four ounces of dicalcim phosphate per barrel of 196 pounds, and the iron pyrophosphate I do not know but it introduces the equivalent of 24 parts per million of FE iron.

By Mr. Goodrich:

Q. You are not a nutritionist?

A. No.

Q. You are not a chemist?

A. No.

Q. Why has your company, or have your companies, selected the whole wheat level for the restoration?

A. I think the answer to that would be to pretty much quote some of the things that were said here yesterday by Dr. Wilder. We feel that No. 1, whole wheat, with its original nutritive qualities, is an important source of these nutritive qualities for people, that flour is an article of food consumed by a large mass of people, many of them in the lower income levels, and knowing as we do that in the processing that it loses these nutritive qualities,

633 we feel that the policy of restoration to original levels, the levels at which nature placed the articles, should be followed.

Q. Then I might quote Dr. Sherwood to the effect that the wheat berry is for the propogation of the wheat plant and not for human beings.

A. And yet we feed human milk to babies, although that was made for calves. I mean, cows' milk to babies, although nature put it for calves.

Q. To what trade does your flour go?

A. At the present time this brand goes to the baker trade. We haven't as yet put this into the family trade, but as I said before our plans are for extension.

Q. Do you have any figures of any kind to show the destruction of vitamin B-1 in the baking process?

A. I don't think that we have.
Mr. Goodrich: I think that that is all.
Mr. Campbell: I think that that is all.

668 Presiding Officer Willcox: Is there any further trade testimony on Section 15 in the proposed regulation? (No response.)

If not, we will turn to Consumer testimony. Is there any consumer here who wants to testify?

Whereupon

HELEN POTTER was called as a witness and having been first duly sworn, was examined and testified as follows:

The Witness: My name is Helen Potter, and I am representing the American Association of University Women. This is an organization of 68,000 consumers.

The American Association of University Women has worked actively for consumer protection, to help to bring about the Food, Drug and Cosmetic Act of 1938, and since that time they have continued their activities along this line.

In their last National Convention in 1939 they passed a resolution that they would work to help strengthen
669 the Food, Drug and Cosmetic Act by helping in any way they could with the enforcement of the Act. In accordance with this resolution, the General Director of the American Association, with the advice of the Social Science Committee, was authorized to send representatives to the hearings on Food Standards.

The Association has worked on the problem of Food Standardization for a number of years through its local study clubs, and through its research staff, trying to learn about the various possibilities in the matter, and to evaluate the various problems from the consumer standpoint, of course, not from the technical, trade standpoint, and thus we are very much interested in the whole problem of standards. We as consumers want all of the information that is practically possible in order to facilitate our problem of purchasing and knowing what we are getting.

When we buy flour to make light bread we do not want to find that it is flour best adapted to pies, or that it is a flour with a high content of bran when we want a very

light flour. In other words, we feel that we would like qualified names on special flour such as pie flour, or high bran flour, coarse flour, high vitamin content flour, with as much information as possible about the special
670 qualities of these types of flour, and that we would like the name "flour" unqualified to be put on the label of flour we are accustomed to buy in the making of light breads and biscuits.

Since it is generally recognized that ash is one indication of the quality of flour, in accordance with the general criteria for standards that have been laid down by the American Association of University Women, we feel that we should have some maximum ash content for the flour, as an indication of what will be included in the identity of the flour.

It seems reasonable, too, that a definite moisture content on which to measure the proportion of ash be established to make this test more accurate.

We are very interested in encouraging all types of technical developments, anything that will improve the quality of flour, the taste of the flour, or the nutritional value of the flour which should be encouraged by all consumers. Yet we as consumers do not know about the various technical problems and ingredients that go into flours, and so that we want as complete information about any new types of flour, any special qualities of flour, that we can have.

We feel that each flour should be labeled to give us the greatest possible information and facilitate our making of choices, so that we can make a choice that will
671 best meet our purposes, and we think that on the basis of information and as complete information as possible, with reference to each type of flour, that each flour can stand on its own merits, and that the label of flour, unqualified, can be made restrictive enough so that it will give us some key to what we are buying.

I think that that is all of the testimony that I have.

Cross-Examination by Mr. Hardenbergh.

Q. What do you mean by the "label of flour unqualified"?

A. If we as housewives go in and ask for flour, we should like to have a flour that we know fairly much what we will be getting. That is, we don't want to ask for flour

and not know whether it will be a flour that is reinforced, or a flour that has bromate in it or a flour that has a high ash content, or a flour with a low ash content, we want a standard that is exclusive enough that when we ask for flour we will know fairly well what we are getting.

Of course we are interested in these other products and we will ask for them when we want them, and I think
that just as now people ask for rayon, they don't ask
672 for silk when they want something that is rayon, and
if we want a flour with reinforced calcium or vitamins, we can ask for a flour that has special standards for that particular type of flour.

Does that answer your question?

Cross-Examination by Mr. Gilbert.

Q. How would the consumer be prejudiced or adversely affected in any way if when she bought flour she received flour to which had been added vitamin B-1 and calcium and iron in amounts to make it equal to those items in the whole wheat?

A. At the present time the flours that have the added qualities that you have named are more expensive, and it means that if a person who is not very familiar with buying problems goes in and asks for flour, they will be, if they are given that flour indiscriminately, they will be charged a higher price than they would have to pay if they bought the flour without these added specialties.

We might cite the example of milk. Some people like to save a few cents by going over to the store and getting their milk without the added cost of door to door delivery, and other people like to pay the extra money and have
the milk brought to their door each morning. There
673 are, of course, certain advantages in having a very
fresh bottle of milk, but lots of people would rather use the money other ways and have their milk maybe 24 hours old when they drink it.

It is the same in the matter of flour. There are very definite advantages to a reinforced flour, but some people may prefer to get their calcium and vitamins and iron in other ways, and I feel that the consumer should be allowed to get what she wants to and it is to facilitate consumer purchases, and we want as much information about the product, we are very eager to have this vitaminized flour

become more commercially prevalent, and it can be bought by consumers, and I think it will be accepted very readily by consumers, but it would be less confusing if we bought it as a special type of flour instead of not knowing whether we were getting that or whether we were not.

Q. Coming back to your milk proposition, isn't it so that milk is irradiated or otherwise treated so as to increase its vitamin D potency and it is still called milk?

A. It is called irradiated milk. If you telephoned the dairy and said you wanted milk, you do not get that special milk.

Q. But the bottle calls it milk. In some bottles,
674 on the label, it might say that it has been irradiated or treated with something else so as to increase its vitamin D.

A. Standards have not been set here for milk yet. There has been no discussion of it, and—

Q. You are not quite accurate on that, are you?

A. Maybe there has been discussion, but the standards have not been set, and I am throwing out this as a matter of what would be valuable to the consumer. If the consumer calls up the dairy and asks for milk, they will ask very likely for Grade A or Grade B or Grade C milk, and they would not want a milk that was much more expensive.

Q. I am told that there has been a standard promulgated for milk, if you will let me check that.

Mr. Campbell: I have one question.

By Mr Gilbert:

Q. No, there has not been, but the consumer would call the store and say, "I would like milk" or "I would like milk that has been irradiated," or something of that sort, and with flour if you say that your sole objection to the restoration of flour is that it would increase the price, and there has been no proof on the record yet that restored flour is not to sell at practically the same price if not the same price as flour, but the consumer there
675 would be informed on the label of the flour bag that there has been a restoration process giving additional nutritive factors, and don't you think that the consumer there has not been injured or prejudiced in any way?

A. No, the consumer has not been injured or prejudiced, and yet it will, I think, avoid confusion, if we have the maximum amount of information on the label, and

thus make the standard for flavor not a catch-all for every type of specialty commodity.

If we open the door to one type of vitamin, one type of product being carried by flour, it might be that we would have many, many different types of ingredients added to flour, and in certain cases it would not be as beneficial, maybe in one case the flour would not be any more expensive, if say, vitamin B were added, but if some other vitamin were added it might be more expensive.

Q. I confine my question solely to the restoration of vitamin B-1 and minerals iron and calcium. I am not asking you about anything else.

Now, such a product with a clear label declaration of the presence of those restored ingredients, I still ask you again, to what extent, or how can a consumer be injured or prejudiced when she buys such a product, called
676 flour, and the label clearly states what these additional factors are?

A. You have to have a safeguard to be certain that there is a minimum amount of these vitamins, or the calcium or the iron in the flour.

If I may interrupt you, confining yourself to the question I asked, the restoration to the limits of the whole wheat, you see that has been the suggestion of some of the witnesses here, that this restoration be at the limits of the whole wheat, in those respects.

A. Well, couldn't that sell as a product of its own, on that particular standard?

Q. What would you call such a product?

A. High vitamin flour.

Q. Wouldn't that be misleading?

Mr. Goodrich: We object to the argumentation on that point and he has asked her different times about what she has in mind and she has answered the question and we object to any argument with the witness on this point and we object to it for that reason.

Mr. Gilbert: If Your Honor please, this witness has stated on behalf of the consumers that she objects to the additional option and ingredients of certain items proposed here and I think it is quite proper to cross examine to explore into this witness' reasons for it, and it is
677 not argumentation by far.

Mr. Goodrich: She has stated that she favored the addition but that the housewife was entitled to know

when she was buying a specialty product that she was buying a specialty product, and not flour, and the question has been gone into two or three times, and it could serve no purpose by extending or argument at this point as to whether it should be put in by optional ingredients or under a separate name.

Mr. Gilbert: Except that we have a right to show whether the objection is meritorious or not and the only way we can do it is to explore into this objection of the witness, and certainly the record should show whether the objection is meritorious or not, and now if counsel strenuously urges that objection, I am willing to have the Trial Examiner sustain it and give us an exception for the record but I think that you are precluding us from finding out whether this a valid objection or not.

Presiding Officer Willcox: I think that I will permit the question, but please confine yourself to the point of trying to make more precise what the witness' objection is, rather than argue with her.

Mr. Gilbert: I am not trying to argue with her.

The Witness: My answer to your question is that
678 it would be less confusing to the consumer if the flour that is restored partially to the nutritive value of whole wheat were sold under a qualified name rather than under the label of just "flour."

By Mr. Gilbert:

Q. I will ask you again, and this Your Honor, is to see whether the witness' objection to certain proposals is meritorious—I ask you again what would you suggest as a name for that?

A. I said, "high vitamin flour."

Q. And I ask you again, do you not believe that such a name would be more misleading than the proposed labeling of certain witnesses here, because "high vitamin" might very well mean that it has got a fortification rather than restoration and it also has minerals which would not be included in high vitamins?

Presiding Officer Willcox: I think that you are going a little far in arguing with the witness, and I think the witness' position is clear.

Are there other specific points about her testimony that you want to bring out?

Mr. Gilbert: I would like to have the record show an exception to your ruling, Your Honor.

679 *Cross-Examination by Mr. Campbell.*

Q. I would like to ask a question, Miss Potter. Your Association, you said, had a good deal to do with, over a period of years, with this law?

A. Yes, it has been working, it worked very actively from 1933 until 1938 when the Food, Drug and Cosmetic Act was passed.

If you go to the hearings on the Food, Drug and Cosmetic Act you will find that the Joint Women's Legislative Committee testified a number of times, both in 1933, in the hearings in 1934, and the hearings in 1935, and that the American Association of University Women was a member of this Joint Legislative Committee of which there were 11 other women's organizations.

The Association's national headquarters are here in Washington, D. C., and when the matter was being discussed in committee and on the floor of the House, there were representatives at many of the open discussions, most of them.

Q. You are familiar, then, with the proceedings in Congress when the law was passed?

A. Yes, I am.

Q. Now, as I understand it, what you are asking for is that there be a definition that will include the
680 product which you ordinarily desire to get under the name of flour, and then those other kinds of flour named by some qualified name, is that right?

A. Yes, that is right.

Q. From your knowledge of those Congressional deliberations, do you think that under the law as it now is framed, you can get that?

Mr. Goodrich: We object to the question. It asks for an interpretation of the law.

(The following discussion was placed upon the record, and later physically stricken by direction of the Presiding Officer.)

Presiding Officer Willcox: Let me see if I can state your question.

Will you please state what in your opinion would be the desirable method in the interest of the consumers, of labeling, the general method of labeling products which are and have been here referred to as flour, but which differ in certain respects from the kind of flour that you speak of as light bread and cake flour?

Mr. Campbell: That is substantially right.

The Witness: I shall interpret that question on the basis of the general criteria of the American Association of University Women, with regard to standards.

681 Their criteria for the setting of standards is that they want the standard to be as usable, as informative to the consumer as possible.

Now, then, if the standard is too inclusive, its usefulness as a standard is weakened. Thus, we should like to have a separate standard set up for many special types of flour.

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687 We realize that if standards are set limitations
688 are put on, that certain flours will be excluded, and of course as consumers we do not want arbitrary definitions that make the price of the commodity go up considerably, yet we recognize that definitions have to be exclusive or else they are no good at all, and where exactly what types of flour will be excluded by the definition is something for the technical experts in the trade, and in the Government to decide, and not for the consumer to decide.

All that the consumer can say to help guide you in this decision is that we feel that the definition should not be broadened, because it would make the standard of identity of less value to us as a guide in buying.

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689 *Cross-Examination by Mr. Haley.*

Q. As a consumer representative, you would prefer to have these products that do not exactly conform to your idea of flour or white flour, if they are supplemented by vitamins or changed in some way, that they do not exactly conform to your idea, you would still prefer to have those called flour of some kind, would you not, modified flour or high vitamin flour or something like that? You expect to call them flour, do you not?

A. It is all right to call them flour if it is qualified so that there is no confusion between that particular flour, and the flour that we have come to know as flour and which conforms to the standards that we are setting here.

Mr. Campbell: That is all.

Cross-Examination by Mr. Goodrich.

Q. I have one or two questions. In your appearance here, are you appearing here pursuant to a resolution of some kind of your Association?

A. Yes, sir.

Q. Is it this general resolution which you have cited, authorizing the Executive Director to appoint repre-
690 sentatives at these hearings?

A. Yes, sir.

Q. No special regulation or resolution has been adopted with respect to these proposals?

A. Not with respect to these proposals because it is impossible for an organization of 68,000 consumers to come together and study this whole problem, but we do have a special research committee, the Social Studies Committee, and a sub-committee of that, the Consumer Sub-committee, which does nothing but study proposals of this sort, and the statements that I make have been gone over with members of that committee, who are appointed by the Board of Directors of the American Association of University Women.

Q. In purchasing flour in a market, I believe that you said that you expected a flour that would make light bread and biscuits. You would not expect, would you, a special pie flour when you bought flour?

A. No, not at all.

Q. Or a coarsely ground product which was suitable for cracker making and pie crust baking?

A. No.

Q. In saying that you favor the use of the word "flour" qualified for specialty products, you have in mind a stand-
ardized product or a product generally known to con-
691 sumers under that qualified name?

A. If a product should come into considerable use, such as possibly this type of vitamin flour, where most of the nutriment value of the whole wheat is restored, I think that that type of flour could easily be standardized and could be commonly known by the consumers, and very likely would be asked for under its own qualified name as readily as they ask for flour, just as the consumer begins to ask for rayon, many more times than she asks for silk.

Q. Do you have something further?

The Witness: Mr. Chairman, could these remarks be incorporated, insofar as they are applicable to the sections, on whole wheat flour, and to the sections on self-rising flour, and farina and semolina?

Presiding Officer Willcox: I don't know how far they would be applicable, and I don't know which questions will arise in connection with those.

The Witness: The general idea.

692 Q. In your opinion should minimum and maximum limitations be placed upon certain vitamins, and minerals added to flour in the interest of consumers?

A. Yes.

Mr. Gilbert: Is she qualified to answer that? I raise that point, and also with respect to bromate. I would like to object to it on that ground.

Mr. Goodrich: I think that she can answer.

Presiding Officer Willcox: Have you made a study of any of these elements in flour?

The Witness: It depends on what you mean by "study". That is I have tried to inform myself about this whole problem as well as I could, in preparation for this hearing, and I have done a little baking myself with some of the new vitamin flour, and found it very successful.

693 Mr. Gilbert: I renew my objection.

Mr. Goodrich: In your opinion, does the protection of the consumer require that where a product is represented to have certain properties of the kind of vitamin properties, that a minimum be placed in order to insure that those properties be there in the flour?

Mr. Gilbert: I still object to that before the answer goes in.

Presiding Officer Willcox: I think that I will overrule your objection to that.

Mr. Gilbert: Will you state your reason for that, Your Honor? That is for the record?

Presiding Officer Willcox: I think that she is qualified to answer the question as now stated, whether or not the protection of the consumer requires a minimum in flours that are repreesnted as containing these products.

You may have an exception to the ruling.

The Witness: That is one of the reasons that in this testimony I have said that we desired these reinforced flours to be set up as individual commodities, so that it would facilitate the setting of minimum quantities of these

various materials added. It is extremely important that the consumer is safeguarded in that way, because they do not want to pay an additional amount for the
694 flour when they are getting an infinitismal addition to the nutritive value, and it is possible that some sellers might be carried away with the advertising features of these ideas, and be tempted to sell an infinitismal amount of nutritive value at an enhanced price.

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700 EDNA VAN HORN, was called to the stand as a witness, and having been duly sworn, testified as follows:

Direct Examination.

The Witness: My name is Edna Van Horn, and I am the Executive Secretary of the Home Economics Association.

The Association has a long and pretty well established record of working for a program of making it possible for the consumer to identify and acquire products that will serve her needs in a special sort of way and in connection with that program we are interested in a
701 procedure to set up definitions and standards of identity in flour.

Do you want me to tell you anything about the Association, and what home economics is?

Mr. Goodrich: I believe that would be nice for the record, if you would show that and show your position.

The Witness: The American Home Economics Association is made up of women interested in problems of the home and family. In the past they may or may not have been technically trained in home economics. A home economist can be trained in child care and development, and can be trained in clothing or textiles, foods or nutrition, economics of the family, and so on, so that when you are talking to a home economist you are not always talking to a nutritionist or someone skilled in physiological chemistry. It covers a wide range, and I wanted to make that clear.

There are approximately 15,000 individual members of our Association, most of them are engaged in some sort of home economics work, at which they earned their living. There are teachers, women in the rural extension service.

home economists in business, directors of cafeterias and such large quantities of services.

I think that that gives you some idea of what they
702 might do, and that isn't the inclusive list.

Are you interested in my qualifications as a witness?

Mr. Goodrich: Yes, please.

The Witness: I came into the Association just two months ago. Before that I taught at Oregon State College in the School of Home Economics, teaching family economics, home management and equipment. Prior to that I was at Columbia University Teachers College, where I had an assistantship, and as an assistant I assisted Helen Judy Bond, who was President of the American Home Economics Association at that time.

It was during that year that I became very familiar with the policies and programs of the Association. Prior to that I was an Associate Editor of Better Homes and Gardens, in which position I had the food and nutrition and equipment and child care and poetry departments.

Prior to that I was in the Home Economics Department of the Kellogg Company, at Battle Creek, Michigan, working under the direction of Mary Barber, and before that I tried to make my living as an economist and statistician, and I did not have home economics training in undergraduate work. In my college training I majored in economics and sociology. I took my Master's work
703 at Columbia in Foods and Cookery, and since then I have studied economics and education and home economics education.

To save time I might say that I am not an expert as a chemist, a lawyer, or a nutritionist. I have baked bread and used flour and directed many enterprises in which as a consumer I have used flour, and I think that I am familiar with the Association's wishes and their program.

As I see it, when the consumer buys flour she is interested in two things, a product that she can use in cooking that will behave in a certain expected way. Secondly, a product that will supply in nutrition a certain expected—not result, but certain expected qualities, or nutritional value, that is the word I want.

For that reason an identity or definition for flour should describe it and limit it in such a way that you can always depend on being able to use it for the purpose that you have in mind.

Now, the difficulty with getting a wide proposal would be that if you could have flour without additional calcium and vitamins and so on, it will behave one way in feeding your family, and if you can have flour that may have vitamins and no calcium, it will do something else,
704 and if you can have flour that will supply maybe as much as half of the calcium you need, and no vitamins it is very different still, so that you get many different products.

In general, I think that our Association would favor the proposals made in Section 15.00. When it comes to optional ingredients, and such things as bromates and bleaches and so on, we have to depend upon the experts and the technicians. On the other hand, if we are going to identify flour as a definite product we would not want such optional ingredients included as flour that would change flour either in its cooking properties, or in its nutritional properties because then you have something else.
705 I might say one other thing. There has been a lot of discussion about improving the diet of the American people by putting various things into flour. As people are interested in improving the condition of the American people, that is all to the good. The problem, as we see it, is how close you are going to identify it. I can't say the proposals of the industry made will make it possible to identify such products if they are all included in one standard of identity.

707 CHARLOTTE CHATFIELD, appeared as a witness on behalf of the Bureau of Home Economics of the United States Department of Agriculture and, being first duly sworn by the Presiding Officer, was examined and testified as follows:

Direct Examination.

The Witness: Charlotte Chatfield, Bureau of Home Economics, Department of Agriculture. My present position is that I am in charge of food composition work, and the duties of the Section are to investigate the chemical composition of foods in so far as it relates to nutritive value. Furthermore, we advise consumers on various food selection problems, the nutritive value of particular foods and the connection of those foods as they apply to the total diet.

Do you want my further qualifications? Education?

708 Presiding Officer Willcox: I think you might state a little more of your qualifications and education.

The Witness: I graduated at the University of Minnesota in 1917 with a B. S. degree and I have worked in the Department of Agriculture more or less continuously since 1918, with the exception of two years teaching, one at the University of Minnesota and one in a high school. I have spent most of the time since 1917 in scientific research in connection with foods and nutrition. Is that enough?

Presiding Officer Willcox: Unless you want to say anything more.

The Witness: The testimony that I have to give has been discussed with other nutritionists in the Bureau of Home Economics and it has been prepared in consultation with them, and so it represents the opinion of several nutritionists in the Bureau of Home Economics. These nutritionists in the Bureau of Home Economics are interested in flour and cereal standards, since we are investigating food consumption, food composition, food selection problems, in the interests of improving nutrition.

In our opinion, a standard of identity for flour, white flour, wheat flour, plain flour, should not be broad enough to allow as optional ingredients without restriction as to quantity, any or all of such substances as thiamin,

709 riboflavin, nicotinic acid and minerals such as calcium and iron that may be introduced for purposes of fortifying the flour nutritionally. This does not mean we object to fortifying or supplementing the flour. However, we do not think it should be altered to such an extent as to make flour a carrier for all of the essential nutrients.

If the cost is not too high and if the substances added are nutritionally important and frequently deficient in the diet, fortification is probably a good thing. In fact, we believe that proposals for fortifying flour, within certain limits and with suitable regulation and standardization, may be constructive.

Three previous witnesses have quoted from Lydia Roberts and I should like to accent a few words from one of these quotations:

"If it could be properly safeguarded, a judicious use of fortification might be of decided merit."

That isn't a complete quotation there. It should have dashes before and after it This states our position if the

safeguards include, among other things, the consideration of cost.

The question of how such a product is standardized and what it is to be called is of considerable importance.
710 Several of the nutrients that are limiting factors in a large number of diets are perhaps to be recommended as appropriate to be used in flour. The change in the character of flour from adding such factors is significant enough to be regarded as a change of identity. Suppose the new product should be called "fortified flour"—and I wish to say here that this isn't an official proposal; I am using it hypothetically—the consumer could then recognize it as a product different from ordinary white flour in its nutritive value. She could rely on it as containing certain supplementary values and there would be a basis for education on its nutritive value.

Fortification should not be incidental, in our opinion. It would be against consumer interests to allow too much latitude in the kinds and quantities of added nutrients. Such a product deserves a separate standard. Any standard for white flour that allows the optional addition of one or a dozen of these nutrients would not promote honesty and fair dealing in the interests of the consumer. Such a standard would tend to confuse consumers and the fortified product might seem to them to be a short cut to a balanced diet.

Nutritionists do not subscribe to the idea that there is any easy road to obtaining a good diet. Most nutri-
711 tionists would oppose creating a standard for a multiplicity of kinds of supplemented flours, each of which was unstandardized and independent of all the rest. It would lead to advertising abuses; advertising claims would tend to be accepted too credulously by some and rather completely discounted by others. Such a standard would tend to nullify the purposes of the standardization.

In general, we should like to advocate promulgation of a standard essentially as simple as that proposed in Section 15, and cover fortified flours under whatever name is suitable in a separate standard.

That is all.

Mr. Goodrich: No questions.

Cross-Examination by Mr. Hardenbergh.

Q. When you say "fortified" flour, you are not using that in the sense of something added over and above being restored?

A. No—using white flour as the base line.

Cross-Examination by Mr. Stroud.

Q. Miss Chatfield, do you think if a flour is fortified in some respects, in one or more respects, and not fortified or below the restoration point in other respects, it could be called a fortified flour and that be descriptive?

712 A. I think that that would not be in line with the suggestion I was trying to make. It would make too many kinds of flours that could be called by a single name, for example, "fortified flour."

Q. I am not trying to say anything, to question you in the way of putting words in your mouth, or anything like that; it is entirely independent of what you said, except that you suggested a thought in mind. For instance, now, suppose you are treating flour with vitamins and minerals substantially along the line recommended by the Council on Foods, which makes fortification in some respects and a partial restoration in others. My thought is, if that could be called "fortified" flour, it would simplify a lot of problems. Do you think it could, or couldn't? Maybe you answered the question a while ago and I didn't get it.

A. I don't know whether that is a legal question. It would not be in line with the suggestion that I attempted to make, to permit of all of the permutations and combinations. One manufacturer supplies one mineral and another one supplies another; and certain others supply one or another vitamin. And if each of those is called "fortified flour," it would be extremely confusing.

713 I was speaking to the point of having certain designation and standardization of a flour, which I called "fortified" because I needed some word for it, and not that I was proposing it.

Q. Of course, that is a big difficulty. We might assume that the Special Dietary Committee might set up some floors and ceilings, if you please on these various ingredients as may be necessary.

A. Yes.

Q. You take "Dairy Rich;" there are hundreds of vari-

ations with respect to protein and carbohydrates, and so forth.

A. You what?

Q. Suppose you take that product which is on the market now, that term is used for a different type of feed-stuff. If the government would set up floors and ceilings for certain vitamins and minerals and you had to stay within that floor and ceiling, and then guarantee the quantity present, there wouldn't be any necessary confusion in calling it a fortified flour, do you think?—if you get what I mean.

A. I think I do. I can't answer yes or no to that. The principle I was trying to bring out is that if they are to be fortified, they deserve a separate standard which shall indicate the kinds and quantities of added supplementary substances.

714 Mr. Strowd: Thank you.

Cross-Examination by Mr. Gunderson.

Q. I believe you heard the testimony of Doctor Wilder and also Doctor Sherwood, with regard to the two levels of calcium enrichment mentioned by those gentlemen, the one being somewhat to a point somewhat higher than restoration, and the other being to the point of restoration. May I ask if the Bureau of Home Economics is ready at this time to state any preference for either of those two levels?

A. Not as a bureau. Anything I answer to that would have to be my own opinion.

Q. Well, we would be glad to have it. I think we would all be glad to hear your opinion. If you prefer, however, we might be able to hear you on it at some future date.

A. I don't know that it would serve a useful purpose to say which of these particular levels of calcium would be better, especially if it led to similar questions on each of the other supplemental substances.

Mr. Gunderson: I am somewhat at a loss to know what is the correct answer to that question.

Cross-Examination by Mr. Haley.

715 Q. If there should be set up a standard of identity for fortified flours, as you have described, would you allow the addition of optional ingredients to that, if placed on the label, or would you restrict it to the present knowl-

edge? How would you arrive at what the proper level should be in a product of this kind, as to vitamins and minerals?

A. I think we don't know enough yet to be able to say what would be, for example, a restored flour. I personally don't like the term "restored." But suppose you were trying to set up a standard for such a product as had been described as a restored flour—is that your question?

Q. Yes.

A. I should think that such a standard should be limited to the kinds and quantities of substances that you find in whole wheat, until there is reason to suppose that the product would be superior to put in some substances that are not present in wheat or present only in insignificant quantities.

750 DR. ELMER M. NELSON, was called as a witness for the Food and Drug Administration and, having been first duly sworn, testified as follows:

Direct Examination by Mr. Goodrich.

Q. Will you state your name for the record?

A. Elmer M. Nelson.

Q. State your address and present occupation or profession.

A. I live in Washington, D. C., and my present position is Chief of the Vitamin Division of the Food and Drug Administration.

Q. Give us, as briefly as possible, a record of your educational attainments and practical experience which qualify you to testify in this hearing.

A. I graduated from the University of Wisconsin in 1918 with a major in agricultural chemistry, and received a Bachelor of Science degree. I received a Master of Science degree from the same institution in 1919.

751 From 1920 to 1923 I was employed as instructor of agricultural chemistry in the University of Wisconsin and I received a Doctor of Philosophy degree in June, 1923. The two following years I was the incumbent of a fellowship in the University of Wisconsin, engaged in studies of the nutritive value of infant diet materials. From July 1925 to April 1926 I was Director of Chemistry and Nutri-

tion for the National Soft Wheat Millers' Association of Nashville, Tennessee.

On April 1, 1926 I was employed by the Department of Agriculture in what was then the Bureau of Chemistry, and from that time to 1935 I was employed both by the agency engaged in the enforcement of the Federal Food and Drug Act and the Bureau of Chemistry and the Bureau of Chemistry and Soils. I was directly in charge of all vitamin assays.

Since 1935 I have been Chief of the Vitamin Division of the Food and Drug Administration.

Q. Do you belong to any professional or scientific societies?

A. Yes. I am a member of the Council on Pharmacy and Chemistry of the American Medical Association. I am a member of the U. S. Pharmacopoeia Vitamin Advisory Board. I am Referee on Vitamins for the Association of Official Agricultural Chemists. I am a member of the American Society of Biological Chemists, and I am Chairman of their Committee on Vitamin Nomenclature. I am a member of the American Institute of Nutrition, and I have just completed a term as Associate Editor of the Journal of Nutrition published by that Institute.

Q. Have you written or had published any document of a scientific nature dealing with vitamins?

A. I have.

Q. You have been here during the testimony with respect to vitamin and mineral additions to white flour, have you not?

A. I have.

Q. Do you believe it to be in the interest of consumers to allow the addition of certain dietary products of that kind to white flour?

A. Honesty and fair dealing in the interest of the consumer would not be promoted by including vitamins and minerals as optional ingredients of flour unless minimum standards are specified for each of the vitamins or minerals that may be used as optional ingredients. I make that statement for this reason: If we have no definition and standard for flour and a manufacturer should choose to manufacture flour and put in, say, one-tenth of a per cent of the minimum daily requirement of nicotinic acid in 6-1/2 ounces of flour, and labeled it flour with nicotinic acid,

753 the Food and Drug Administration could readily ascertain it was mislabeled. However, if we have a definition and standard for flour and nicotinic acid is recognized as one of the optional ingredients, if a manufacturer should put in only a trace of nicotinic acid he would be complying with the requirement of the law if he labeled it as flour with nicotinic acid. Therefore, it would seem necessary that if vitamins and minerals are to be included as optional ingredients, minimum standards should be specified.

Do you wish me to continue?

Q. Yes.

A. Testimony has been offered at this hearing that the purpose of adding these optional ingredients which are intended to improve the nutrient value of bread is to benefit the public health. Now, if flour which is fortified with vitamins or minerals is to serve that purpose, it becomes important that a substantial quantity of the vitamins or minerals should be added. I do not believe that the desired objective can be reached by restoration of flour as described by Dr. Wilder.

If we consider only the addition of calcium to white flour to the extent to make it equal in calcium content to whole wheat flour, we would then have roughly 10 per cent or less of the minimum daily requirement of calcium, and 754 that is not accomplishing the purpose for which these vitamins and minerals should be added. There should be some very definite improvement of the diet if such additions are to be of advantage to the consumer.

Neither do I subscribe to the view expressed by Dr. Wilder that vitamins should be added to a type of food in which you expect to find that vitamin. If people were actually guided in the manner that he suggested, they would choose whole wheat bread if their diet was insufficient in Vitamin B-1, rather than white bread, and we would have no necessity for fortification of white flour as has been here expressed.

I think there are other more important considerations in guiding us as to what vitamins should be added to flour. Of prime importance is the question of whether flour is a suitable carrier so that the vitamin will not deteriorate, either in the flour itself or after it has been subjected to any cooking or baking process.

Also of prime importance is whether the food which has been fortified with the vitamin and mineral actually reaches

the group of people who should be benefited. It has been testified here that dietary deficiencies are more likely to occur in low-income groups, and I concur in that opinion. Therefore, the foods which will reach those groups should be fortified, if any foods are to be fortified with vitamins or minerals.

It has been testified that the average intake of flour is approximately 6-1/2 ounces a day, and I think we may use that figure for further consideration. According to Dr. H. C. Sherman of Columbia University, in his book entitled "The Chemistry of Food and Nutrition", one ounce of flour will supply 100 calories; therefore, 6-1/2 ounces would supply 650 calories. That is approximately one-fourth of the caloric requirement of adult man. A man in an office occupation probably requires 2,500 calories a day, and if he is moderately active he probably requires 3,000 calories a day. Therefore, 6-1/2 ounces of flour will provide about one-fourth of the caloric requirement.

If the addition of vitamins and minerals is to serve a useful purpose, it seems to me that if any vitamin is added to flour it should provide about one-fourth of the minimum daily requirement of that vitamin, and the same is true of minerals.

On the basis of what I have said before, I would suggest the following figures as the minimum quantities of certain vitamins and minerals which should be added to 6-1/2 ounces of flour:

For Vitamin B-1, 65 units.

For Riboflavin, one-half milligram or 500 micrograms.

756 For Nicotinic Acid, 2½ milligrams.

For Vitamin D, 100 U. S. P. units.

For Calcium, 200 milligrams.

For Phosphorus, 200 milligrams.

For Iron, 2½ milligrams.

Q. For Vitamin B-1 you mean 65 international units?

A. Yes, international or U. S. P. units.

Q. And the units of Vitamin D are the same?

A. Yes I am suggesting those figures as being approximate values which may be used for this purpose.

Q. Do you have anything further to add?

A. My opinion is that these vitamins and minerals should not be optional ingredients of plain flour, but they should be optional ingredients of a flour that is designated by name in some way to indicate that the food value of

the product has been changed or improved. I don't know any nam to suggest for such a product. Of the names that have been discussed here, I don't believe "Restored" is a proper name; and the terms "Fortified" or "Reinforced" I don't think are quite appropriate. I think the term "Enriched," used by Dr. Gunderson, comes closer to expressing what such a term should express.

I have a further statement to make with reference to the quantities of those vitamins or minerals that should be added. I think it is perhaps equally important to set
757 a maximum limit on the quantities of these vitamins or minerals to be added to flour, and I say that for this reason: Some years ago when minimum standards for Vitamins A and D in cod liver oil were prescribed by the Pharmacopoeia, manufacturers started to make claims for higher and higher vitamin content of their cod liver oil. There is, as you can appreciate, certain commercial advantages in claiming a higher vitamin content for the oil; and I am afraid if no upper limit is set for these optional ingredients we may have the same situation develop as to these optional ingredients in flour. I see no reason why it would be necessary or desirable in any instance to add more than four times as much of any of these vitamins or minerals which I have mentioned.

Q Doctor, a number of additional substances have been suggested and recommended for use in the addition of vitamins and minerals to flour. Among those are processed wheat germ; wheat germ oil; Vitamin A or its precursors; Vitamin C or ascorbic acid; Vitamin B-6; pantothentic acid, and so forth. You have not enumerated those in your suggestions?

A. I have not.

Q. Can you give us your reasons for not suggesting those?

A. May I ask that you enumerate them one at a time?

758 Q. Processed wheat germ up to one per cent?

A. I see no objection to the addition of wheat germ. I don't know what is meant by "processed" wheat germ. I know that there is such an article on the market, but I don't think it is a common name for an article of that kind. I see no objection to the use of wheat germ or any of the other milling products of wheat to fortify Vitamin B-1.

Q The next was wheat germ oil, said to contain Vitamin E, the amount added being one-tenth of one per cent.

A. I would certainly not recommend the use of wheat germ oil as an optional ingredient in flour to provide Vitamin E. Very little is known about human requirements for Vitamin E. It is most difficult to determine Vitamin E accurately. It has to be done by biological methods that require perhaps more time than is consumed in the determination of any other vitamin; and the quantity of Vitamin E that would be supplied by flour containing one-tenth of one per cent of wheat germ oil would appear to me to be insignificant, even if the Vitamin E were retained in that oil, but it appears to me that oil in such small quantities, distributed in flour, would be readily oxidized and the Vitamin E would not be retained.

Q. There is, as I understand it, no definite infor-
759 mation with respect to the human needs for Vitamin E?

A. There is no definite information as to the quantity which may be needed. There is some information that at least suggests that the vitamin is needed.

Q. Is it your opinion that the addition of one-tenth of one per cent of wheat germ oil could have any effect upon the taste of a flour or bread?

A. I don't believe I could answer that question in a way that would be worth much to you. It would seem to me that such a small quantity of oil would be very difficult to taste.

Q. Do oils of the same type generally have much taste, if you know?

A. Vegetable oils, as a rule, are judged a better oil if they are free from taste.

Q. The next was Vitamin A or its precursors.

A. I do not believe that flour is a suitable carrier for Vitamin A, because Vitamin A is prepared in the form of concentrates. The precursors are available in free form, but the Vitamin A itself is not available in free form. In concentrates, they would not be expected to be stable when added to flour. They would be subject to oxidation and destruction, and would be further subject to oxidation and destruction when subjected to baking. What I have said with reference to Vitamin A applies equally to Vita-
760 min C.

Q. With Vitamin C ascorbic acid is included?

A. Yes. The Vitamin C would probably be more stable

in flour than A, but it would be more subject to destruction if the flour were subjected to baking.

Q. Vitamin B-6 has been suggested as an optional ingredient in this "restored"—or whatever you want to call it—flour.

A. I think we might consider Vitamin B-6 and pantothenic acid together. We have some information as to the value of those vitamins in preventing certain deficiency diseases in experimental animals, but we have inadequate information with respect to what value that may be, if any, in human nutrition, and we know nothing about the minimum requirements of those substances, and have not adequate methods for determination that would be suitable for control purposes if those vitamins should be added to flour.

Q. In your opinion, would there be any marked difference between the addition of Vitamin B-1 by the incorporation of thiamin in mill stream, high in Vitamin B-1, or the addition of Vitamin B-1 by the addition of thiamin chloride?

A. No; they serve the same purpose.

Q. Should Vitamin B-1 be added in synthetic form, 761 what potency should that product have?

A. If added in synthetic form, it would be presumed it would be the pure vitamin. I think we could be guided as to purity by the definition of Vitamin B-1 in the U. S. Pharmacopoeia.

Q. With respect to the addition of riboflavin, Vitamin B-2 or Vitamin G, in what form should that be added?

A. It has been suggested here, or there has been testimony here, that it is being added in the pure form and also in the form of some concentrate. There would be no objection whatever, it seem. to me, to adding riboflavin in pure form, and I believe there are suitable concentrates that are available for increasing the riboflavin content of flour by such addition. It is my recollection that Dr. Sherwood testified the concentrate they were using contained approximately ½ per cent of riboflavin, and such a concentrate would seem to be suitable provided it contained nothing in any way injurious or deleterious.

Q. What is the common and usual name of riboflavin, if you can tell us?

A. Riboflavin is the common name. The terms Vitamin B-2 and Vitamin G have been used, but those terms have

also been used in a different sense, and considerable confusion has been caused by the use of those terms, and
762 it was for that reason the term riboflavin was adopted.

Q. With reference to the addition of nicotinic acid, is that the common and usual name of that ingredient?

A. That is the common and usual name of that ingredient, yes. There is nicotinic acid and nicotinic acid amide, which both have the same physiological function.

Q. Is it known under other names?

A. The name pellagra preventive factor was suggested for the substance we now know as nicotinic acid. Before, it was not known that nicotinic acid had qualities for preventing or curing the disease pellagra.

Q. Nicontinic acid exists in the pure form, and it is in that form that you recommend it be added?

A. Yes. And I might state that so far as riboflavin and nicotinic acid are concerned, they are also described in the U. S. Pharmacopoeia, and the degree of purity required in those standards might be a suitable guide for the purity of the substances to be used if they are used as an optional ingredient in flour.

Q. Riboflavin is in the Pharmacopoeia too?

A. No; riboflavin is not in the U. S. Pharmacopoeia.

Q. Nicotinic acid is?

A. Yes, sir.

Q. The Vitamin D, in what form is it added, or is
763-765 it advisable to add it to flour?

A. I don't know that I have anything to add to the testimony of Dr. Scott.

Q. All calcium compounds are not suitable for addition for nutritive purposes to flour?

A. No. Some may be toxic.

Q. Which calcium compounds are suitable for that purpose?

A. I can't enumerate all that may be suitable.

Q. Just give us some that will serve the purpose for which they are desired in this connection.

A. Various calcium phosphates; calcium carbonate may be used, in part at least; calcium lactate; those calcium salts generally recognized as suitable ingredients of foods.

Q. Is the same general testimony true with reference to the addition of compounds of phosphorus?

A. Yes.

Q. And what compounds of phosphorus would be suitable, do you know? Calcium phosphate and what else?

A. I don't know of any others being used. There would be no objection to using sodium or potassium salts of phosphoric acid, but it may be likely they are unsuitable for use in flour for bread-making.

Q. What compounds of iron are suitable for addition?

766 A. There are various inorganic salts of iron that are suitable. I don't know what would be suitable to use in flour, whether phosphates, chlorides, or salts that might be considered to be suitable.

Q. Can you give us any information with respect to the stability or destructibility of Vitamin B-1 when used in flour and when subjected to the baking process?

A. Recently some examinations of flour and yeast were made in our laboratories, and I don't know the definite figures, but I am sure the destruction of Vitamin B-1 would not exceed 20 per cent. There was some destruction of it.

Q. That was in the baking process?

A. That was in the making process, yes. We determined the Vitamin B content of the yeast to be used, and the Vitamin B content of the bread after baking.

Q. Can you add anything for the record as to the relative destructibility of Vitamin B-1 in alkaline solution?

A. No. We have conducted no studies to determine what losses there may be due to baking. It would seem there would be some loss of Vitamin B-1 in the baking of bread if the bread was alkaline in reaction.

Q. Do you deem it in the interest of consumers to prevent the product from reaching an alkaline solution?

767 A. If that is necessary. I don't know to what extent it is necessary, but if it is, I think such precaution should be taken.

Q. Proceeding to riboflavin, that is recognized as a relatively stable vitamin, is it not?

A. It is stable to heat.

Q. It is stable to heat?

A. Yes.

Q. Is that likewise destructible in an alkaline solution?

A. Not as readily as Vitamin B-1. On the other hand, it is readily destroyed by light, but I don't know if that is important in this connection.

Q. What can you say as to the stability of nicotinic acid under those same conditions?

A. To the best of my information, nicotinic acid is a sufficiently stable compound that the possibility of loss due to baking or most of the treatments which flour may undergo in the home is rather remote.

Q. And is the same testimony true with respect to Vitamin D?

A. Yes.

Mr. Goodrich: I think that is all the examination we have at this time.

Mr. Campbell: I don't feel equipped to cross
768 examine this witness.

Cross-Examination by Dr. Strowd.

Q. There is just one question I would like to ask. You stated certain figures as the minimum quantities of certain vitamins and minerals which should be added to 6½ ounces of flour?

A. Yes.

Q. In the case of Vitamin B-1 you stated the minimum was 65 units for 6½ ounces?

A. That is right.

Q. I just want to get this clear for the record: Do you refer to addition rather than the amount in the flour, in setting up those minimums?

A. I had reference to the amount that the finished product should contain.

Q. Then would you say it would apply to 100 per cent flour, what we call enriched flour?

A. Not if it conformed with the definition and standard for plain white flour, I don't think it would be proper to call it an enriched flour. But if that product had to be made in a different way so that it didn't conform to that definition and standard, then I think it should be classified with these other products. I don't necessarily approve of the term "enriched" for such a product, if such a
769 flour is to be included with this group.

Dr. Strowd: That is all.

Cross-Examination by Mr. Thode.

Q. I know that that maximum figure which you were suggesting was rather an arbitrary one for putting some kind of a lid on these ingredients. You would not recommend, would you, in the case of Vitamin B-1, a maximum which would exclude a restoration to the level of what might be present in a whole wheat flour itself?

A. I don't see the necessity of using whole wheat flour as a base here. That is not our objective if we are concerned with public health. I am of the opinion that it wouldn't be advisable to go more than four times the figures I have suggested.

Q. But it happens you could have more Vitamin B-1 present in whole wheat flour than would be the permitted maximum, if you followed that suggestion.

A. I believe that would be true, that you could have a whole wheat flour that would have more than that.

Q. If you were to have a standard which conformed to the suggestion you made here, would it be your opinion that a flour which had been enriched as you suggest with respect to riboflavin in the minimum amount you have
770 specified, should be entitled to the use and the privilege of that standard name if just in one respect it has been so enriched, or would you require that the extent of enrichment be shown on the label?

A. I think you will see later that it is the intent of the Food and Drug Administration to have regulations promulgated which will provide for further labeling of such a product. I think in the particular instance you give, it would be necessary to show the product contained riboflavin and how much, in addition to using the name under which these products would be designated.

Q. It would be your opinion that if it conformed in only one respect it would be as much entitled to the name as if it conformed in all respects?

A. Yes. I don't see how we could take any other position.

Mr. Thode: That is all.

Redirect Examination by Mr. Goodrich.

Q. I don't think Mr. Thode understood how you got the figure for Vitamin B-1. It was not an arbitrary figure, was it?

Mr. Thode: It was the four times that I said was arbitrary.

The Witness: The four times would be approxi-
771 mately the minimum daily requirement of those vitamins, and there wouldn't be any need to add more.

Mr. Goodrich: That is all.

Recross Examination by Dr. Sherwood.

Q. You said that your suggestion of the amount of Vitamin B-1 that might be added was based on the relationship between caloric intake and Vitamin B-1 intake, is that correct?

A. Yes.

Q. Had you taken into consideration the fact that only about one-fourth of the total caloric intake, according to some nutrition workers, is acquired in the form of flour or some other grain product, and the other three-fourths caloric intake comes from other sources?

A. That was the basis I used.

Q. Then if we get our other three-fourths from other sources, isn't it reasonable to assume it may be desirable and in the best interest of the consuming public to incorporate in flour some of the Vitamin B-1 which is not found in the other sources of calories? I might say that I am referring specifically to sugar. It is true, isn't it, that we must have Vitamin B-1 to complete our metabolism of carbohydrates; and if we have a high intake of sugar in our diet, isn't it reasonable to use flour as a car-
772 rier of Vitamin B-1, to take care of the lack of Vitamin B-1 in sugar?

A. I am offering no objection to using a figure higher than I have given here, but I see no necessity of adding more than the daily minimum requirements to any one product, such as flour.

Q. I think your point is well taken with respect to the minimum in flour with respect to calories. I am a little concerned over the maximum you suggested of four times the minimum, simply because natural products made from wheat now on the market contain in excess of four times the minimum. Would you want to see anywhere in the standards a limitation that would exclude such products?

A. We aren't setting up a definition and standard for anything but flour at this time, and it wouldn't exclude

anything that would come under the definition of flour, as I can see.

Q. I think you are probably right there, that four times would not exclude flours under the white flour definition.

There is just one other question I would like to ask you to keep the record straight, or to complete the record, and that is respecting the use of different sources of vitamins.

You indicated a concentrate of riboflavin. Would you
773 or not approve a concentrate of thiamin and a concentrate of nicotinic acid if available commercially and reasonable in price, and if it was in the best interest of the consumer to use a low-price product for this means of fortification, assuming they contained no deleterious substance?

A. It is difficult to answer that without having a clear understanding of what might be considered a concentrate of thiamin or a concentrate of nicotinic acid. I don't see that there would be any serious objection to the use of such concentrates, but for the time being I don't see why they should be considered, because according to my information there is no available source of nicotinic acid of high potency that is as low as the synthetic materials.

Q. I have been led to believe, from information that has come to me, that it may be possible that a concentrate of thiamin might be available at a reasonable price, and I wanted to get your views on the subject for that reason, and not because there is such a product available now. You stated you would not object to a concentrate provided it did not contain deleterious substances. That was the sole purpose of my question.

A. Well, I don't want to be placed on record as excluding any possible concentrate that may be developed.

774 Q. There is one question I would like to ask respecting your experience with bread containing added thiamin. I assume it is probable when different experiments are made in different laboratories the bases for those experiments may not always be the same. You indicated you had results which showed some 20 per cent decomposition of thiamin; is that correct?

A. I said I didn't recall the exact figures, but I know the loss was not as great as 20 per cent. It may be substantially less than that.

Q. I possibly misunderstood you.

A. But there was a measurable loss of Vitamin B.

Q. Yes. I testified myself to that effect yesterday, that there is a measurable loss, and the experience we had when we used pure thiamin or thiamin in mill stream seemed to be within the range of 10 per cent.

Recross Examination by Mr. Hardenbergh.

Q. If we have a standard for enriched flour, in order to comply with the standard for enriched flour, would it have to contain all these vitamins you have indicated, or would it be an enriched flour if it contained any one or more of the optional ingredients? I am not clear as to just what your idea is.

A. It would be such a flour with one or more of
775 the optional ingredients.

Q. And the label would show which one?

A. Yes.

Q. And when you say from one to four times, the label would state the amount?

A. That is not something we can deal with under a definition and standard here.

Q. I am just trying to get at what the idea is. I am trying to get at this time from the practical point of view of what we would have to do.

(Discussion off the record.)

Q. Might I ask you, Doctor, take this list here, which of these would you consider as the most important vitamin for enriched flour, taking into consideration what you know of the price of the different vitamins and flour as a carrier reaching the people that we want it to reach? How would you list these in the order of their importance? Is iron particularly important, and so on?

A. I can't list those in the order of their importance. The disease pellagra is no more, or no less, important to the person who has it than beriberi is to the person who has that. If you are going to add something to prevent those diseases, I wouldn't be able to list them in the order of importance when we consider the advantage to the consumer.

776 Q. As I understand it, there isn't much point in our putting Vitamin D in flour for people in Southwest Texas, for instance, where they have a lot of sunshine?

A. I agree with that.

Q. What would you put in self-rising flour for people in the South? How would you list those things for self-rising flour for people in Georgia?

A. I am not going to recommend any of these vitamins and where they are to be used or why.

Q. As I say, I am not trying to make you go on record. I am trying to develop the facts from a practical point of view, and point out that there may be need for certain vitamins in certain territories and other vitamins in other territories?

A. That is true.

Q. So that reinforced flour, to accomplish the purpose in view, would be different for one section of the country than in another section?

A. It might very well be.

Mr. Hardenbergh: Thank you.

Recross Examination by Dr. Strowd.

Q. Would you consider the wheat germ which has been partly dried in heat, but not heat sufficient to destroy Vitamin B-1, as a suitable product to be used in the 777 the flour to be enriched by vitamins or minerals?

A. Yes, as far as I know, the product as you have described it, I see no objection to its use for the addition of Vitamin B-1.

Dr. Strowd: That is all.

Presiding Officer Willcox: Are there any other questions?

Recross Examination by Mr. Haley.

Q. There is nothing in your testimony to indicate exclusion of natural vitamins or minerals from the wheat, is there?

A. No. I think we should be concerned with the vitamin or mineral content of the finished product.

Recross Examination by Mr. Thode.

Q. I would like to know whether, in your opinion, it will promote honesty and fair dealing in the interest of consumers to apply this suggested standard or definition, by whatever name it may be known, to a flour which has

been enriched or improved to the minmum suggested level in one respect, such as, for instance, the improvement of a patent flour, perhaps 4½ units of Vitamin B-1 per ounce to the 10-unit level, or riboflavin alone to the minmium you have suggested?

778 A. It isn't possible for me to visualize what would be accomplished by such a product. The testimony has been that the purpose of making such an addition is to be of some benefit to the public health, and that vitamin deficiencies are more apt to occur in low-income groups. Therefore, if the price was not such that it would reach those low-income groups likely to suffer from those deficiencies, then it would not be in the interest of the consumer.

779 Mr. Campbell: Mr. Presiding Officer, on behalf of the Millers National Federation, I desire to make a request as a formal motion, that the record with respect to Section 15,000 be kept open and the hearing postponed until a future date to be fixed by the Presiding Officer.

My reason for this request and the purpose for this motion is that the Millers National Federation, up until a few days before the date of this hearing, had understood that optional ingredients such as vitamins, for example, could be added to flour, and other flour mill products, if the products were designated by a distinctive name, and properly labeled as a mixture of flour and other named ingredients.

A few days prior to the date of this hearing, we were informed that the Food & Drug Administration had taken the position that the product would still purport to be flour and therefore could not be legally sold unless it conformed strictly to the standard of identity promulgated for such product.

Under this informal administrative ruling of which our first notice was, as I said, received only a few days
780 before the date of this hearing, we were advised that when the standards of identity are officially promulgated, the ingredients provided for in the standard, either as optional or specific, will be exclusive and that no ingredient not provided for in the standards will be permitted, even though such added ingredient is declared on the label.

The Millers National Federation had also assumed that

even after the standard on flour was fixed, we could continue to sell flour which did not fall within the prescribed standard and definition of flour by the use of an appropriate descriptive adjective in connection with the word "flour". We understand that the Food & Drug Administration holds a contrary view.

Immediately upon receipt of notice of the position of the Administration, we sent out a special bulletin to all members, advising them of it. In this special bulletin, which is dated August 30, among other things we stated, "Millers who add vitamins to flour and self-rising flour, or who use any self-rising flour ingredients, other than soda and monocalcium phosphate, or who reintroduce into flour a treated wheat germ product, or who add anything to flour and other flour mill products which is not listed in
the proposed standard, should prepare themselves im-
781 mediately to attend the public hearing at Washington
September 9, 1940, and present evidence to indicate the ingredients they use, the volume of production of the products containing such ingredients, the purpose of such ingredients, and the consumer acceptance of the products containing such.

"Time now does not permit the Federation Committee on Definitions and Standards to give you this information, and therefore we will have to rely on individual members to come to Washington to present evidence in behalf of their special products."

Now, the Millers National Federation represents the Milling Industry. We don't claim that we represent all the individual members, but we feel that if this hearing can be postponed as to these questions under Section 15,000 that we would have an opportunity to crystalize the opinion of the various members of the industry, with the hope that we can offer some constructive programs, not only in consultation with our own members, but, perhaps, in informal conferences with the Department; and we think that it will be to the public interest and the interest of the Department if the record can be kept open and the hearing postponed to a date about 60 days from now, to give us this opportunity.

Speaking just for myself, I don't know anything about
these vitamins. The first time I heard anything about
782 them was when I came down here. I feel sure that
if we could have this additional time, we could perhaps arrive at some common ground on which this whole

question could be presented in such a manner as to be helpful to everyone concerned, the Department and the public and the eventual consumer.

Mr. Goodrich: Mr. Campbell, do we understand you are now accepting our position on the law instead of the interpretation of the law that you said you had formerly?

Mr. Campbell: My position on that is that we will have to proceed, probably, on the assumption that your interpretation of the law is correct. But I could not foreclose myself about going to court on that.

Mr. Goodrich: Yes, but for the purpose of receiving additional evidence, we are assuming our interpretation of the law is correct?

Mr. Campbell: Yes, sir; and I might say, this is not derogatory to the Administration—that in the informal conferences with the Department it was rather tacitly assumed by our representatives that the Department at that time was of a similar mind as our own with respect to the interpretation. That does not have to go in the record.

837 FRED BORRIES was called as a witness for and on behalf of the industry and having been first duly sworn, was examined and testified as follows:

Direct Examination by Mr. Campbell.

839 Q. And you desire to make a statement with reference to your position in this matter?

A. Yes. We have been making, since about the first of the year, a self-rising flour with magnesium carbonate, calcium carbonate, in addition to soda, salt, and monocalcium phosphate.

Probably I would have done better if I had brought a chemist or technical man up here, but we were so much interested in this thing that I came up myself, and if there are any technical questions on this which I can't answer, I presume there will be a lot of them, I would like to get our own chemist up here if necessary.

I think that we are the only company that is making a self-rising flour of this kind, and I will give you the reasons

that we have, and as they were given to me, and the
840 reason we made the decision to add these additional ingredients:

Calcium, we have been able to supply a liberal amount of calcium in a normal diet in which Obelite, which is a name that we give for these ingredients combined is used, and second we have equal quantities of calcium and phosphate present.

Dr. Sherman stated in his Chemistry of Food and Nutrition, Fifth Edition, page 292, "Observations upon several species have indicated"—

Q. You are quoting now, from "Observations?"

A. Yes.

Mr. Goodrich: May we take a five minute recess?

(Whereupon there was a recess.)

Presiding Officer Willcox: We will proceed.

The Witness: Our reasoning in the addition of calcium carbonate to the level which we have in Obelite flour has been twofold. First, we are able to supply a liberal quantity of calcium in a normal diet in which Obelite is used and second, we have equal quantities of calcium and phosphorus present.

Dr. Sherman states in his Chemistry of Food and Nutrition (5th edition) page 292:

"Observations upon several species have indicated
841 that during rapid growth and calcification it is well that the food as a whole should have a calcium phosphorus ratio somewhere between 1 and 2."

This means that growing children should have as much calcium as phosphorus in their diet and it may be advisable to have as much as twice the quantity of calcium compared to phosphorus. He goes on to state that the relation of calcium to phosporus can be somewhat lower in the adult but that

"the calcium phosphorus ratio of the whole body is a little under two —"

That is nearly 2 calcium to 1 phosphorus.

Other investigators confirm Dr. Sherman's statements. Bethke, Kick and Wilder working at Ohio State University report in the Journal of Biological Chemistry 98, 389-403:

"The most favorable calcium phosphorus ratio for growth and bone formation was between 2 and 1."

That is 2 calcium to 1 phosphorus.

They also state:

"When the calcium phosphorus ratio was changed from 1.00 to 0.25, growth was depressed."

We have attempted to approach in Obelisk containing Obelite the optimum calcium phosphorus ratio which has been placed at from 1 part calcium to 1 part phosphorus to 2 parts calcium to 1 part phosphorus.

Chemistry of Food and Nutrition by Sherman, page 842 284, states:

". . . . . so that the intake of about 1 gram of calcium per day which was found necessary to insure optimal retention represents a desirable allowance to provide for individual differences."

Chemistry of Food and Nutrition by Sherman, page 293:

"The phosphorus requirement is shown to be .88 grams per day."

These two facts give a desirable calcium phosphorus ratio near 1 to 1.

The other ingredient that we have added is magnesium carbonate and that is to help the flour retain over a period of storage time the fluffy characteristics of the flowability which it has when it is milled, and it also tends to make a fluffier biscuit at the time of baking. Since the first of the year we have sold about half a million dollars worth of this self-rising flour, so that, with these ingredients in it, it represents a large part of our business, and also something in which we are very deeply interested; to endeavor to merchandise this flour without calling it flour, or without calling it self-rising flour would be practically impossible.

The flour costs us about 3¼ cents a barrel more than
self-rising flour would cost if we used the regular
843 ingredients, and we sell it at the same price which is
a differential of 25 cents a barrel over plain flour.

I believe that is all of the testimony that I want to give, Mr. Campbell.

Dr. Strowd: I would like to ask one question, Mr. Borries. Do you think that the average self-rising flour, I mean the normal self-rising flour, of course you are not a technical man but is it the opinion of your technical men that the normal self-rising flour is deficient in calcium?

The Witness: No, we don't think it is deficient but we think it is a condition that will not do any harm.

Dr. Strowd: That is all.

Cross-Examination by Mr. Goodrich.

Q. Mr. Borries, the only purpose for the addition of magnesium carbonate is for the fluffiness?

A. That is right. Well, it also helps to, or acts as an alkaline reagent the same as soda to a certain extent, and does not entirely displace the soda but displaces a certain amount of it.

Q. What quantities do you add of that, if you know?

A. Here, we have got it right here: To 1620 pounds of flour we add 24.3 pounds of phosphate, which is anhy-
844 drous phosphate, and 34 pounds of salt, 16¼ pounds of soda, 7 pounds of calcium carbonate; 3 pounds of magnesium carbonate, and before we used this new formula, our formula with the same amount of flour used the same amount of anhydrous phosphate, 1620 pounds of flour, and 24.3 pounds of anhydrous phosphate, and 34 pounds of salt, and then we had 20¼ pounds of soda, which has now been displaced by 16¼ pounds of soda, 6 pounds of calcium carbonate and 3 pounds of magnesium carbonate.

Q. You understand, Mr. Borries, that magnesium carbonate is a recognized drug?

A. No, sir.

Q. It is not?

A. I don't know. I don't understand anything about it. I never did hear of it being used as a drug.

Q. You don't know whether or not you would get the same effect by using it as by taking milk of magnesia?

A. I couldn't answer that.

Q. Has your company conducted any experiments with this from a pharmacological standpoint?

A. Well, we had the approval of our three chemists. One is a miller now, and in addition to that, we all agreed that it was perfectly all right and then we have been using it since December.

Q. Are any of those chemists also pharmacologists?
845 A. I don't think so.

Q. What is the purpose of the addition of calcium carbonate, just to add the calcium in the nutritive form, supplement the dietary?

A. Yes, sir.

Q. And then the leavening is to come from soda, salt and monocalcium phosphate?

A. No, the leavening comes from, the salt has nothing to do with the leavening.

Q. It would be the soda and monocalcium phosphate?

A. Except that the calcium carbonate and magnesium carbonate take up a part of the work that the soda is supposed to do.

Q. Do you know what function they play in that respect?

A. As I understand it, they are just an alkaline agent that forms carbon dioxide with the phosphate.

Q. But they are not added primarily for leavening effect, or are they?

A. They are leavening agents but that is not the reason they are added, or not the entire reason.

Q. Is it your opinion that the necessity of this calcium carbonate addition is to work out a more favorable calcium phosphorus ratio in the flour?

A. Yes, I think that we have added something
846 there to the flour that makes it better. It is no additional cost to the consumer, and we think it is a better flour, and we should be allowed to call it self-rising flour and continue to merchandise it.

Q. And I didn't get exactly the ratio in reading that; I didn't have an opportunity—

A. We tried to approach a 1 to 1 ratio.

Q. What is the normal in self-rising flour, without the addition of calcium carbonate?

A. I couldn't answer that. It is less than that, though.

Q. How do you buy anhydrous monocalcium phosphate, under a brand name?

A. Yes.

Q. V-90?

A. That is right.

Q. Do you also buy the monohydrate, mono-calcium phosphate?

A. Yes, we buy that, too.

Q. And under what name is that sold?

A. We buy that from another company, the Monsanto Chemical Company. I think that they have got some trade name for it—"H-T."

Q. But it is sold as monocalcium phosphate?

A. I would like to add here, Mr. Goodrich, if I
847 could, that, this has not anything particularly to do with our case right now, that two summers ago we conducted quite some experiments with the use of pyro acid phosphate, in addition to mono-calcium phosphate, in our self-rising flour, and we found that during the hot

weather where the flour was hot and probably the ingredients, either water or milk, and the shortening was hot, that we obtained a much better biscuit by the addition of pyro acid phosphate than we did from the straight mono-calcium.

We could only use a certain amount of this pyro-acid on account of its taste and when this anhydrous phosphate was brought out almost two years ago, then we decided not to use this pyro acid phosphate any further, and we were just using it in one brand, very much as an experiment.

It had a delayed action, but we doubt whether it is any better now than the anhydrous phosphorus, but I wanted to bring that up because in the definition proposed by the Government they made no provision for anything but mono-calcium phosphate and it could be very easily seen that in time to come when we would want to use or someone would want to use pyro acid—

Q. Do you know of anyone using pyro acid phosphate?

A. No, I don't, not now.

848 Q. And why was it necessary to use that only in hot weather?

A. That was the only time that we thought the dough was moist and the weather was hot and we had this combination of moisture and heat which tended to bring about a reaction between the phosphate and the soda.

Q. That reaction would not result in baking, ordinarily?

A. Well, they would lose a certain amount of the gas strength before the dough was put in the oven.

Q. I take it that your experience with it was unsatisfactory?

A. Well, it is just like a lot of those things, we don't know whether it was bad or whether it was good. The new phosphate came out and we didn't try it any more, but our experiments showed that it should have been satisfactory, and down in the South they use—a lot of them use this cottonseed oil for shortening, and of course they didn't have any ice boxes, a lot of people that used self-rising flour, and they had hot flour and probably hot shortening and maybe hot milk.

Q. Arriving at the amount of your calcium additions, what considerations dictated the amount to be used, just this ratio?

849 A. I don't think that I am in a position to answer that any further than I have, Mr. Goodrich. If you want to, I can have our chemist come up here, but that was the result of their experience, and their suggestions.

Q. Is it their idea to supply any certain amount of the minimum daily requirements of calcium for the human being?

A. I don't think so. In 6¼ ounces, an individual's average daily consumption of flour, 750 milligrams of calcium, I expect that they did have that. I don't think that I ought to answer that. I would rather have my chemist answe st.

Q. How much more calcium is there in your special flour than in the ordinary run of self-rising flour, if you can answer that, sir?

A. Let Dr. Strowd answer that, if you please. (Discussion off record.)

The Witness: Calcium carbonate is .41 per cent—that is considering the entire mixture as 100 per cent.

By Mr. Goodrich:

Q. Mr. Borries, could you make biscuits with a product such as yours, where calcium carbonate and mag-
850 nesium carbonate was substituted for the sodium bicarbonate in self-rising flour?

A. I don't believe that I would want to. I don't know.

Q. You would recommend the use of all of them together rather than separate ingredients?

A. Yes, sir.

Q. When introducing this new product to the trade, under what name and what information did you give the consumers as to the relative advantages of the product?

A. We introduced it as Obelisk self-rising, with Obelite added, and then we had on the sack that Obelite was a copyrighted name for an intimate mixture of phosphates, also sodium carbonate and magnesium carbonate.

Q. Was the average consumer informed as to the meaning of any of those terms, or what the reaction of those ingredients would be?

A. Yes, we had an advertising campaign, a newspaper advertising campaign that I would be glad to give you. I have got them up at the hotel, copies of that advertisement, if you would like to have it.

We have submitted that to some other officials of the Food and Drug department, and we would be very glad to give it to you if you want it.

851 Q. You understand, Mr. Borries, that we don't like to be put in the position of having to ask for all of these things. If you want to present them you can present them but we would rather not request it. Any action that is taken by the Administrator necessarily has to be based on the evidence of record at the hearing and since the evidence is not available to us, it is up to your people to present it.

Now, we don't want to take the position of requesting it, and—

A. Well, it seems to me that we are all here for the same reason and of course if you want to be technical we would probably have to bring some technical food and drug nutritionists up here. We have been making this flour since December, and we have talked to different members of the Food and Drug Administration about it, and it was my impression that if we came up here and showed that we had an article which we had been making for some eight months and on which we had a considerable business, that unless there was some objection to it why the definition would probably be continued, and now then if you want me to bring our chemists up here, in order to give you the technical reasons as to why we think that magnesium carbonate and calcium carbonate are satisfactory, we would be very glad to do it because we have
852 such an investment.

* * * * *

889 PROCEEDINGS.

Presiding Officer Willcox: We will proceed, please.

In regard to the motion made yesterday to hold the record open for certain purposes, that motion will be granted, in accordance with the suggestions yesterday, and the record held open for the introduction of further testimony in regard to the addition of vitamins and mineral products, mineral substances, to flour, in whatever form the regulation may take.

That is, I will not make any suggestion whether it should be by optional ingredients or what form.

The continued hearing will be limited to that group of questions unless for due cause shown it is otherwise ordered at that time and I want to make clear that merely additional cumulative evidence that may have been pre-

pared in the meantime would not be considered sufficient cause for going into other questions at that time.

I should feel that there would have to be a very definite reason shown why any evidence other than that was not presented at the main hearing in order to justify any departure from that limitation.

In regard to the date the adjourned hearing then will be set for Tuesday, November 12, 1940.

1000 PROCEEDINGS.

Presiding Officer Willcox: Are you ready to proceed?

Mr. Goodrich: Yes.

Presiding Officer Willcox: Are you ready, Mr. Campbell?

Mr. Campbell: Yes, sir.

Presiding Officer Willcox: Unless there is some objection, I think we will proceed with the farina, Section 15.080, of the proposed regulation. I understand that the Government will be ready later in the day to complete the case in regard to self-rising flour, subject to the questions that are being held open until November 12th, and at that time it will be convenient to have the further testimony on the industry with regard to self-rising flour.

Is there any objection to that procedure?

(No response.)

You may proceed.

Mr. Goodrich: Off the record here.

(Discussion off the record.)

Mr. Goodrich: We will call Mr. Joseph Callaway, Jr.

Whereupon

MR. JOSEPH CALLAWAY, JR., was recalled as a witness by and on behalf of the Food and Drug
1001 Administration and, having been previously duly sworn, was examined and testified further, as follows:

Direct Examination.

Mr. Goodrich: Mr. Callaway has been sworn and has testified previously in this hearing, and his qualifications appear under the general testimony given at the first part of the hearing.

The Witness: Are you going to read the Section?

Mr. Goodrich: I guess I had better.

(Thereupon, counsel for the Administration read Section 15.080 of the proposal.)

By Mr. Goodrich:

Q. Mr. Callaway, does the food described in Section 15.080 have a common or usual name?

A. Yes. The common or usual name for this product is farina.

Q. What did your field investigations develop with respect to current practices in the preparation and merchandising of farina?

A. During the course of the surveys on flour previously described, representatives of the Food and Drug Administration found that farina was being manufactured in many of the mills which also manufactured flour. As a rule, it was made from hard wheat, although in some instances, particularly on the Pacific Coast, it was found to be manufactured from soft wheat.

A similar product is made from durum wheat, known as semolina. Red durum wheat was not found being used in any of the plants visited in the manufacture of farina.

The wheat was cleaned, as has been previously described in the manufacture of flour. The process for manufacture of farina is the same as that described for flour except that the farina is withdrawn from the process before the particles of endosperm from which the bran coat and germ has been separated have been reduced to the small particle size of flour.

The ash content, as in the case of flour, was found to be generally used as a measure of the degree of separation. Particles of endosperm from which the bran coat and germ have been almost completely separated, but which are too large, to pass through 10 XX silk bolting cloth, are withdrawn from the process of making flour.

The size of the particles varies from those which are just retained on a 10 XX silk bolting cloth, which has approximately the same size openings as No. 100 woven wire cloth, up to particles which just pass through a No. 20 woven wire cloth. Particles larger than able to pass through a No. 20 woven wire cloth are, as a rule, unsuitable for farina since the bran has not been sufficiently removed.

1003 During the course of the investigations a number of samples of farina were collected. They were examined in the field laboratories of the Food and Drug Administration for moisure, ash and protein by methods previously described for the determination of these constituents in flour. They were then examined for particle size by the passing through sieves according to the method prescribed in paragraph (b) (2), Section 15.080. The results of these examinations were reported to me and I have had them tabulated as shown on table XVII, of Government Exhibit No. 3.

Q. What raw material is used in the preparation of farina?

A. Wheat other than durum or red durum. The same condition with respect to unavoidable mixtures of durum and red durum would occur here as in the case of flour since the method for manufacturing flour and farina in the first stages of manufacture are the same. The same limit as to the admixture of these wheats in the manufacture of flour would therefore be reasonable in connection with the manufacture of farina.

Q. What use is made of farina by consumers?

A. It is used largely as a breakfast food and also as one of the farinaceous materials used for preparing macaroni.

1004 Q. What are the essential characteristics which distinguish farina from other products and which render it suitable for use by consumers as farina?

A. In my opinion, the essential characteristics are the type of wheat from which it is derived, the degree of separation of the bran coat and germ, the size of the particles, and the moisture content.

Q. What stages does the wheat go through in the manufacturing process?

A. The wheat is cleaned, as I have described, is tempered, ground, put through sieves to seperate the particles of like size. Certain of these are reground. Bran particles are removed by sifting and blowing, and flour removed from the large size particles by bolting, the particles of the desired size separated and combined as farina.

Q. To what degree of fineness are the purified middlings reduced in the preparation of farina?

A. To such a size that they will pass through a No. 20

sieve or woven wire cloth but will not pass through a No. 100 sieve or woven wire cloth.

Q. By what method can the degree of reduction be determined with reasonable accuracy?

A. By sifting the product on sieves fitted with No. 20 woven wire cloth and No. 100 woven wire cloth. Such 1005 a method is outlined in Section 15.080.

Q. That is paragraph No. 2—(b) (2) of Section 15.080?

A. Section (b) (2); yes.

Q. Is that method in general use today by food chemists?

A. Yes.

Q. What is the significance of and the factual basis for the provision which contemplates a small tolerance for these particles appearing in farina which will pass through a No. 100 sieve?

A. When farina is made in the mill the particles which will pass through No. 100 sieve have been removed, since the product has been bolted on top of 10 XX bolting cloth. However, in handling the product small amounts of flour are broken off of the particles and since the standard is applicable as long as the product is in interstate commerce, some tolerance for fine particles is reasonable.

Q. In your opinion, based upon your experience with farina and upon the information which you have obtained from field investigations, and sieving tests which have been made, what is a reasonable requirement as to the size of the particles in farina?

A. I believe it reasonable to require that all par- 1006 ticles should pass through a No. 20 sieve but that not more than 2.5 percent should pass through a No. 100 sieve.

Q. 2.5 percent?

A. 2.5 percent. That is the blank; where we have the blank percent here, you may place 2.5 in there.

Q. That is the tolerance which you have just testified about?

A. Yes.

Q. What degree of removal of bran coat and germ from the endosperm is required to render the product suitable for use as farina?

A. This is somewhat difficult to say. However, in gen-

eral, consumers have come to expect farina to have the bran removed to a point where only a few specks of bran can be seen in the finished product. Bran removal cannot be adequately gauged, however, by observation but the ash content measures it with reasonable accuracy.

Q. In your opinion, based upon your experience and information secured under your direction, what is a reasonable maximum ash limit for farina?

A. I believe a reasonable ash limit is .5 percent.

Q. Explain why you place it at that figure and give the factual basis for such a figure.

A. As testified to in the case of flour, the ash content of the bran is roughly about twenty times the ash
1007 content of the endosperm varies somewhat but experience has shown that where farina has been made in the usual way it will contain about .30 percent to .45 percent ash. By allowing .1 percent to take care of variations, we would secure what I believe would be a reasonable limiting figure of .5 percent.

Q. How do you determine the ash content?

A. By the same method that has been previously described under flour. It is given in the book "Official and Tentative Methods of Analysis of the Association of Official Agricultural Chemists," Fourth Edition, 1935, page 207, under "Method I—Official." This method, however, is used by analysts of the Food and Drug Administration and a great many other analysts, and is generally used for the purpose of determining ash.

I might say that method for determining ash also is given in the Fifth Edition.

Q. You have testified in the testimony with respect to flour where that method appears in the Fifth Edition?

A. Yes; I thought I might just put it here. It appears in the Fifth Edition on page 212, under the heading "Ash, Method I—Official."

Q. Is that the method used by analysts of the Food and Drug Administration in this connection the same method they use for determining the ash content of flour?

1008 A. Yes.

Q. Is the moisture content an essential characteristic of farina?

A. Yes. All farina will contain some moisture depending on the moisture content of the wheat from which it is

made. This may be changed considerably by tempering of the wheat.

Q. What effect has excess moisture in farina?

A. It would have the same general effect as in flour. It lowers the keeping qualities and changes some of the characteristics of farina depending on the quantity of moisture present.

Q. How do you make laboratory determinations of moisture?

A. In the Food and Drug Administration moisture is determined by drying the product according to the method prescribed in "Official and Tentative Methods of Analysis of the Association of Official Chemists," Fourth Edition, 1935, page 206, under "Vacuum Oven Method—Official." That appears in the Fifth Edition on page 211, "Moisture and Direct Method, Vacuum Oven Method—Official."

Q. That is the same method you described in your testimony with reference to the determination of moisture in flour?

A. Yes

1009 Q. What, in your opinion, is a reasonable maximum limit upon the moisture content of farina?

A. I believe the reasonable limit is the same as that which will be allowed in flour, namely, 15 percent.

Q. Why do you fix it at that point?

A. I believe in general that the same considerations should apply to farina as to flour. Probably not quite as much moisture is lost in the milling process in farina as in flour, but the difference is not material, in my opinion, and the same moisture limit should be applicable.

Q. Do you believe that the proposed definition and standard of identity if promulgated as a regulation with a tolerance for small particles that you have indicated would promote honesty and fair dealing in the interest of the consumer?

A. Yes.

Q. Why?

A. It would definitely establish the difference between farina and the product made from durum wheat, semolina; would fix the size of the particles to conform with what is now recognized as generally satisfactory; would hold the moisture to a reasonable limit.

The ash content would require a reasonable degree of purification.

Q. In what way does this proposed standard de-
1010 viate from the old advisory standard?

A. It permits farina to be made from soft wheats whereas the old standard does not and it more definitely fixes the size of the particles.

Q. What is the significance of that deviation?

A. The significant difference, in my opinion, is the provision with respect to the use of soft wheat. The use of soft wheats has become somewhat general in the West and apparently they give a satisfactory product for use as farina.

Q. What will be the probable effect of the proposal if promulgated as a regulation with the tolerance you have suggested?

A. It will cause very little change in present trade practices with respect to the manufacture and sale of farina.

Q Is it your opinion that the standard is a reasonable one, from the standpoint of the manufacturer?

A. Yes, I believe it is.

Mr. Goodrich: I believe that is all.

Mr. Campbell: I haven't any questions, but I think maybe Mr. Roberts has.

Cross-Examination by Mr. Roberts.

Q. I really only have one question to ask Mr. Cal-
1011 laway, and that is, in naming the ash limit at .5 per-
cent, although there are a very limited number of samples developed in Table XVII in excess of that, have you really felt from your investigation of the merchandising of farina that the public's conception of it is what we call technically "purified middlings", in line with the previously accepted definition of farina as purified middlings from wheats other than durum?

A. There are a certain number of samples of a product which might have been considered to have been sold as farina, which had an ash limit higher than the one I propose. These products, however, obviously were not purified to the extent of those that have an ash limit of less than .5 percent. They are dark in color, due to the adhering bran, and as a rule, they are used as ingredients of breakfast foods, where other ingredients are also used.

I do not believe the person, the consumer, who has bought farina as such, understands what we might call

the partially purified product could be farina. This proposed standard would limit the name "farina" to what might be called the light-colored product.

Mr. Roberts: That is all I have.

Cross-Examination by Mr. Hardenbergh.

Q. Mr. Callaway, have you any figures to indicate
1012 how much breaking-down of the particles in soft wheat farina there might be due to transportation and so forth?

That is, suppose you started out with 2 percent fine particles. Have you made any test as to what that might be when it gets shifted around in interstate commerce?

A. Well, we have not made any special investigation on that point. However, it is not our theory that it should start out with 2 percent. It is our theory that it should start out with only the small amount which might be much less than 2 percent.

From the limited data on these soft wheat farinas which can be picked out of Table XVII, particularly from the State of Washington, there are some soft wheat farinas where the protein is down relatively low. The amount passing through the 100 mesh sieve is usually in excess of the hard wheat farinas.

Q. Are these samples picked up from the mills?

A. They were shipped across the country, picked up at various places; but the sample was shipped to Washington and the sample probably had as much motion as the products, but I couldn't say what the relation would be of stuffs that would come in from the sample and from a big bag.

Mr. Goodrich: You mean shipped from the State of Washington?

The Witness: Yes, this "Washington" here is the
1013 State of Washington.

There are some soft wheats in the State of Oregon, too, and they are well within the proposed tolerance.

Presiding Officer Willcox: Will you explain why there is such a difference in the proposed ash limitation between farina and flour?

The Witness: Well, farina is a highly purified product.

Presiding Officer Willcox: More highly purified than flour?

The Witness: Much more highly purified than the type of flour recognized by the standard. If farina were ground up, it would give a highly purified white flour, which would be recognized as a patent flour, which is a highly purified type of flour, whereas the proposed standard for flour includes flours of much less purification.

Presiding Officer Willcox: Are there any further questions of this witness?

(No response.)

You are excused.

(Witness excused.)

Mr. Goodrich: I will call Dr. Munsey back to the stand.

Whereupon

1014 DR. VIRELL E. MUNSEY was recalled as a witness for and on behalf of the Food and Drug Administration and, having been previously duly sworn, was examined and testified as follows:

Direct Examination by Mr. Goodrich.

Q. Doctor, are you familiar with the food product commonly and usually known as farina?

A. Yes.

Q. What raw material is used in the preparation of farina?

A. Wheat other than durum or red durum.

Q. What are the essential characteristics of farina which distinguish it from other products and which render it suitable for use?

A. Farina is a granular product of relatively uniform particles with very little flour. It is this granular nature which renders the product suitable for special uses.

Q. What do consumers use farina for?

A. Macaroni production and breakfast foods principally.

Q. Tell us of the manufacturing processes applied.

A. In the milling of wheat the miller desires to produce much of the endosperm in granular particles called middlings, which are later ground to produce the best
1015 portion of the flour. These middlings after passage through a machine called a purifier, in order to remove particles of bran present before being ground into

flour, can be collected and are the product known as farina.

Q. To what degree of fineness are the middlings reduced in the manufacturing process?

A. These middlings are reduced to such a degree of fineness that they will pass through a No. 20 woven wire screen and not through a No. 100 woven wire screen.

Q. By what method can the degree of reduction be determined with reasonable accuracy?

A. The degree of reduction can be determined by the method described in this section.

Q. That is, Section 15.080, subsection (b) (2)?

A. That is right.

Q. Is that method in general use today?

A. I couldn't say this method is in general use today, but it is used by the Food and Drug Administration. However, methods similar to this are in general use to determine the particle size.

Q. This method is a practical one from the enforcement standpoint, is it not?

A. Yes.

Q. What is the significance of, and the factual basis for, the provision contemplating a small tolerance
1016 for the particles appearing in farina which will pass through a No. 100 sieve?

A. The use of farina in macaroni manufacture and breakfast foods demands a very small amount of flour in this product. It is for this reason that the amount of flour is limited.

Q. Are you familiar with Table XVII of Government Exhibit No. 3?

A. Yes.

Q. Did you make or check any of the sieving experiments reported there in that table?

A. Yes.

Q. Did you make them or check them?

A. I think I only checked those that were reported. I made some, I think. I made a good many that were not reported in this particular table here.

Q. Tell us of the work you have done which pertains to the provisions of the proposal relating to the size of the particles appearing in farina.

A. The test used as stated under whole wheat flour, is an adaptation of a method used for testing particle size in cement. In the study of the application of this method

it was necessary to examine a considerable number of samples.

Q. Did you examine those samples?

A. That is right. That is what I was referring to 1017 a minute ago.

Q. In your opinion, what is a reasonable requirement as to the size of the particles of farina?

A. A reasonable requirement on particle size for farina would be small enough to pass through a No. 20 woven wire screen but too coarse to pass through a No. 100 woven wire screen. Since it is impractical to prevent the presence of some flour, a reasonable allowance is made for 3 percent flour which passes the No. 100 woven wire screen.

Q. You agree with Mr. Callaway's testimony that when the product left the mill, there is practically no flour in it and the flour develops in the shipping process?

A. That is true. Generally in good commercial practice there is a small amount of flour at the time of production.

Q. What degree of bran coat and germ removal is required to render the product suitable as farina?

A. Bran and germ removal should be as complete as practicable under good manufacturing practice.

Q. How can you gauge with a reasonable degree of accuracy the extent of removal of bran coat and germ from endosperm?

A. The degree of removal of bran and germ is determined by the amount of ash.

1018 Q. The amount of ash in farina?

A. That is right.

Q. In your opinion, based upon your experience and the experimentation which has been conducted by the Food and Drug Administration with respect to the proposal, what is a reasonable maximum ash content limitation for farina?

A. A reasonable maximum ash content of farina is 0.5 percent.

Q. In fixing it at that figure, do you have in mind determinations made by the method prescribed on page 207, under Method I—Official, of the "Official and Tentative Methods of Analysis of the Association of Official Agricultural Chemists," Fourth Edition?

A. Yes.

Q. That is the method which has been described by Mr. Callaway?

A. That is right.

Q. Do you believe that the proposed definition and standard of identity, if promulgated as a regulation with tolerance for small particles which you have suggested, and with the ash limitation you have suggested, will promote honesty and fair dealing in the interest of consumers?

A. Yes.

Q. In your opinion, would such a standard of
1019-20 identity be a reasonable one from the manufacturer's standpoint?

A. Yes.

Q. What would be the probable effect of the proposal if so promulgated as a regulation?

A. Nearly all the products purified by the required removal of bran demanded for macaroni and certain types of breakfast food will conform with this proposal. Some of the samples which would not conform with this ash limit contain too much bran and germ to be considered purified to the extent desired in farina and would be excluded under the proposal.

Mr. Goodrich: That is all of the direct examination.

Mr. Campbell: No questions.

Mr. Goodrich: I move at this point that we incorporate Mr. Gunderson's testimony of Saturday into the record.

Presiding Officer Willcox: It will be so ordered.

Mr. Campbell: Does that complete your testimony?

Mr. Goodrich: Yes.

(The following testimony, which is inserted at this juncture upon instruction of the Presiding Officer, was
1021 given on Saturday, September 14, 1940, by the witness, Frank L. Gunderson.)

Whereupon

FRANK L. GUNDERSON was called as a witness for and on behalf of the Industry and, having been first duly sworn, was examined and testified as follows:

Direct Examination by Mr. Campbell.

Q. State for this record that you have been qualified, and that your qualifications appear at a certain place in the record.

A. I have been qualified on a previous occasion in this

hearing, and my qualifications appear in the record, I believe on page about 430.

Q. Under the testimony with respect to Section 15.000?

A. Yes, sir; under Section 15.000 and other sections discussed in this, wherein certain testimony has been given which is applicable, or, even in some respects, more applicable to Section 15.080 and following, on this identity.

I therefore respectfully request that in regard to the matters of the vitamin or mineral additions, and such other respects as the Chair, in its discretion, should entertain at the adjourned hearing, the record on Section 15.080,
1022 be left open and that all testimony heretofore given on vitamin and mineral additions to white flour under Section 15.000, including the testimony of Drs. Nelson, Sherwood and Scott, and my own testimony, be reintroduced and made formally applicable, in so far as it is pertinent to the consideration of the same questions of vitamin and mineral additions in Section 15.080.

Of the vitamin and mineral ingredients requested for nutritional improvement of flour, I believe that especially the schedule offered by Nr. Nelson should be approved. This includes vitamin tests B_1, B_2, D, and nicotinic acid, and the important dietetic minerals, calcium and iron.

Vitamin A and its precursors, Vitamin B and Vitamin C, and even Vitamin K, which I believe has not been mentioned here this week, are of secondary interest in flour, and can be held in abeyance pending further clinical and technical development.

Regarding the matter of what may be proper nutritional amounts of the adjuncts for addition to unit weight of farina, I have no arbitrary or rigidly fixed quantities to recommend. Testimony in this hearing and other testimony stated in the hearing on another proposed regulation, namely 403-J of the Food and Drug and Cosmetic Act, will tend to clarify the reasonable and proper levels. And, to my mind, consideration of establishing proper enrichment of the level, is the recognition of the amount
1023 which is a normal daily serving portion of the particular food.

Attention is deservedly mentioned also to the effect that farina, although used as a food for the whole family, is one of the first so-called solid foods to be fed to babies, starting off at the fourth or fifth month of the baby's life.

Vitamin D is a very useful dietary constituent, especially in tooth and bone building.

Vitamin D has been added in carefully regulated amounts to the farina of my company since April, 1932. The food product to which I refer is known country-wide to the public by the clear front panel package labeled as "Quaker Farina Wheat Cereal enriched with Vitamin D".

I show you here samples of the latest forms of packages of two different sizes, to suit the customer's or consumer's convenience. On the back panel of the package is a statement in clearly legible type, which explains the mode of enrichment, namely, "Contains 400 U. S. P. units of Vitamin D. per ounce supplied by approximately the addition of 1.5 of 1. percent irradiated dry yeast."

Irradiated dry yeast bought on contract from a yeast manufacturer of highly reputable standing, and its laboratory facilities are suitable to assure uniform Vitamin D potency, guaranteed at 7054 U. S. P. analysis Vita-1024 min D units per gram.

At the request of my company, we sponsored at least four years ago, medical and clinical tests of this irradiated yeast with children, under the immediate supervision of research physicians of the University of Chicago with excellent improvement in the health of the children.

The final pulverized irradiated dry yeast is a rich source of Vitamin D, and contains also Vitamin B_1. Because of the particular manner in which the yeast is dried, there is no enzymatic capacity of the yeast. This dry irradiated yeast is not unpleasant in taste, and is a highly pleasant edible adjunct, and is so recognized by nutritionists.

The sales of farina amount to millions of packages a year, and its economy makes it widely available.

Regarding sieves, I believe it is satisfactory to require, as printed in the August 3rd Register, that it be based on No. 20 sieve. As the maximum amount which may pass No. 100 sieve, I suggest either 2.5 or 3.2 percent is acceptable.

Q. 2.5 or 3.2?

A. Yes. The printed suggestion in the Federal Register, I believe, suggested 3 percent as the maximum limit. While the proposed maximum ash range of 0.45 percent to 0.65 percent might be acceptable for non-enriched 1025 farina, it stands to reason that the ash content would be markedly higher as the mineral improvement is raised or affected.

It has been calculated, for example, that if one ounce of farina with an ash content of 0.50 percent were en-

riched with dicalcium phosphate so as to bring the calcium content of the nutritionally improved farina to 187 milligrams of 1/4 of the daily requirement, as it has been proposed in the Federal Register of September 5th, in a daily portion of farina, which, I repeat, is generally considered to be the one ounce, then the ash content of the final product is in the neighborhood of 2. percent.

I am not certain that a maximum ash standard is necessary. If one is adopted, I suggest that provision be made to permit reasonable mineral enrichment with optional nutritional ingredients.

Mr. Campbell: Off the record, please.

(Discussion off the record.)

The Witness: I was referring to the special dietary proposals in the Federal Register, particularly the section which suggests certain figures representing the minimum daily requirements, or the different age groups of people.

Presiding Officer Willcox: Are there any questions from anyone present?

1026-7 *Cross-Examination by Mr. Goodrich.*

Q. In connection with this ash proposition, I get it that it is your idea to get the ash in what you might term natural farina, with a provision for higher ash to take care of mineral or vitamin properties which might be added. Is that it?

A. That is entirely correct.

Q. You start with the natural basis of 0.5. That would be satisfactory to you?

A. That is entirely satisfactory to me.

Q. You feel the ash limit should be measurably increased if it is continued into the regulations from the proposal?

A. Yes, I feel that that is essential, in order to permit reasonable and judicious nutritional enrichment of the food.

Q. Is it not also possible that with such an increase in the maximum ash limitation you would open the door for makers of the low-grade farina to include an unusual amount of the bran coat and germ in the completed product, which is not desirable in farina?

A. Yes. That thought has occurred to me, and I, frankly, have no good solution to offer for that difficulty.

Perhaps some of the other witnesses who follow later may have some. I don't know on that point.

1028 Q. You deem it essential that the natural ash coming from the bran coat and germ and the other part of the wheat should be limited in order to characterize a product known as farina?

A. I am not sure it is necessary for that purpose, because in my six years of experience as Assistant State Chemist, it occurs to me that fibre content should be considered as a possibility for alternative regulatory purpose.

Q. Can you suggest a figure for maximum fibre content to fix in the regulation in order to obtain the result which you deem desirable?

A. No, I cannot, and I want this clearly understood: My answer was merely my first reaction and I have not had opportunity to consider it as thoroughly as might be advisable.

Q. I don't know that I understand you exactly.

Is it your position that a minimum degree of separation of the bran coat and germ from endosperm is not necessary in the product of farina?

A. I don't know what to answer on that at this moment. I would rather—I think a more considered opinion would be suitable under the circumstances.

Q. The product is known sometimes as purified middlings of wheat, is it not?

1029 A. I believe that is correct.

Q. By that, it means some separation of the bran coat and germ from endosperm?

A. Well, I think that the very public acceptance of a white product would require use of a light-colored product, which would preclude the possibility of a manufacturer allowing dark specks to crop into the product. That is, be milled into the farina.

Once a manufacturer has a product established as a light-colored farina, it is for his own welfare to keep the product uniformly light-colored.

Q. Is your company now making any addition other than Vitamin D to farina?

A. Only as B_1 and B_2 vitamins, and some other vitamins of the B complex, natural to yeast, which are introduced, incidentally. But I should like to endorse the nutritional principle that, I think, in the light of current knowledge, it is entirely reasonable that light farinas might well

be enriched with other nutritional adjuncts than Vitamin D—and, in addition to Vitamin D.

Q. Has the addition of a nutrient in the form of dry yeast also increased the amount of material that would pass through the bottom sieve, No. 100 sieve?

A. Yes, if the agitation is sufficient it is entirely possible that the finely pulverized yeast could be shaken
1030 off the wheat endosperm granules, but you will note the amount used is a very small fraction of 1. percent.

Q. It would not change your provision for that tolerance?

A. Your assumption is correct.

Q. Your company at present does not think that there is sufficient addition of the vitamins other than Vitamin D, or minerals, which you have suggested, in your present product, to warrant a label statement that those ingredients are included in the finished product?

A. That is correct. The amount of B_1 and B_2 introduced incidental to the D conveyed in the irradiated yeast are so small that we have felt unjustified in making any specific claims for the B_1 and B_2, which is introduced.

Q. You are not adding any of the calcium or phosphate, or iron compounds at this time?

A. We are not.

Q. And nicotenic acid?

A. We are not.

Q. You testified that Vitamin D in properly and carefully regulated amounts has been used by your company for addition to farina since 1932? What do you mean by "carefully regulated amounts"? Can you give us any information on that subject?

A. I mean by that that each bag of irradiated dry
1031 yeast as it comes to us carries a label stating the potency of the material in terms of Vitamin D. Each batch of farina is made in a batch mixer after carefully weighing the amount of the non-enriched farina on the one hand, and the irradiated dry yeast, on the other hand; and a specific portion of irradiated dry yeast is introduced with a specific portion of non-enriched wheat endosperm, and the two are thoroughly mixed in a machine especially suitable for that, found suitable through thorough investigation of different portions of the batch as the final product comes from the mixer.

Q. Have you deviated the amounts used from below 400

U. S. P. units up to the present standard of 400 U. S. P. of Vitamin D, and have you gone above 400 units at any time?

A. Yes. In 1932, when the process was started, the yeast was of lower potency. The degree of activation obtainable in the production of dry yeast was not so effective as today. Furthermore, the clinical thought on the matter at that time was quite different than it is today, and so; in consultation with pediatric specialists, the conclusion was reached that the amount should be so fixed that each ounce of Quaker farina was to provide 45 so-called Steenbock units of Vitamin D.

There was no such thing as U. S. P. or Interna-
1032 tional unit of Vitamin D at that time.

I might say for the record that the conversion factor accepted today is the Steenbock unit times 2.7 which is equivalent to U. S. P. or International units. So, therefore, in 1932, we were really adding 121 U. S. P. units of Vitamin D per ounce of farina.

A few years later, some rat laboratory tests indicated, in conjunction with other small animal laboratory tests, and a few clinical tests on irradiated ergostral solutions, that Vitamin D might not have the same antirachitic effect in children as an equivalent amount used in cod liver oil, which was looked upon a standard.

The factor in Vitamin D was considered to be 1-to-3. In other words, it was considered that 3 units of irradiated ergostral yeast in Vitamin D may be sufficient to do the same work as the vitamins in cod liver oil. Therefore on clinical advice of the specialists, the amount per ounce of Quaker famina was raised to 1000 U. S. P. units per ounce, and there it remained for several years. Then, further specific tests on irradiated yeast with children, under medical supervision, showed that that species discrimination did not, in fact, prevail, and so, accordingly, the level was reduced to what is now looked upon as a more reasonable dosage, or amount, of the Vitamin D, suitable for a day's feeding portion.

1033 Q. How did it increase from the equivalent of 125 U. S. P. units up to 400 U. S. P. units? You took it from 125 up to 1000 and then back down to 400?

A. Yes.

Q. Why did it not go back down to 125?

A. That is a very good question and is explainable in this way: In the early years of Vitamin D, Dr. Steenbock,

who was my major professor, considered that there were 13.3 of what later became known as the Steenbock unit in Vitamin D in a gram of cod liver oil. As years went on, the cod liver oil quality of Vitamin D improved, and when the standard was set a few years ago, instead of being set at 2.7 times 13.3, it was set at 84 U. S. P. units. It was the natural consequence of the improved quality of cod liver oil, and, at the same time, conditioned by pediatric and other medical opinions.

Does that answer the question?

Q. Yes.

Has it deviated from 400 U. S. P. units, either above or below, since that time?

A. No, sir.

I wish to state again that we do not choose to be arbitrary in this. We will welcome the advice and knowledge that comes forth from this hearing, and from the hearing to start on October 7th, to which I have already re-

1034 ferred.

Mr. Goodrich: I think that is all.

Presiding Officer Willcox. Any other questions?

Cross-Examination by Mr. Lehman.

Q. Couldn't the problem of ash be taken care of by referring to farina as a purified product?

A. I don't know, but I would be glad to hear your comments on that.

Q. I am talking about if they are purified by the so-called purifiers in the mill that would remove all the specks that you mention.

A. Yes; the branny particles and the other layer, the bran germ.

Q. In other words, purified, ready for screening?

A. Well, I was thinking, Mr. Lehman, of the regulatory officials' problem. I do not know how the regulatory officials could discriminate between ash incidental to the endosperm itself and ash contributed by nutritional additions.

Q. Well, you want to get an ash on the farina, as such, to set the standard on farina. Then you want to make an allowance, and as you say, 0.5 of 1. percent would be a fair representation in ash in farina.

A. Yes.

1035 Q. I understood Mr. Goodrich to ask how to prevent the introduction of a lower grade material. That is why I bring up the question; if we are to have purified middling of the wheat product, that would take care of it.
A. Yes; I quite agree with you.

Presiding Officer Willcox: Would you then define "purified middlings"?

Mr. Lehman: Well, that is a standard in the industry. I don't think there is any question about that. Or "clean middlings," if you wish.

Presiding Officer Willcox: Are there any further questions?

Cross-Examination by Mr. Goodrich.

Q. There isn't any standard degree of purification of the middling by the mill, is there? Do they all have the same ash?

A. No; that would vary with the crop and perhaps also slight variations in the variety of wheat.

Q. Also vary with the mills handling the product in making the purification, would it not?

A. I should think it might.

By Mr. Lehman:

Q. Is it not a fact that you purchase your product on specifications and purchase it on the outside?

1036 A. Yes, indeed. When we purchase farina on the outside, that is, when we do not mill it ourselves, we purchase on specifications, and you can be assured we are very specific in what we want. We don't want a variation in the product and a shipment of farina which contains speck extraordinary to the tradition of the product would be rejected forthwith.

By Mr. Roberts:

Q. Dr. Gunderson, are your specifications usually based on a cycle, rather than a technical description?

A. I can't answer that, Mr. Roberts.

By Mr. Goodrich:

Q. On what specifications do you buy in order to obtain a product which has the proper degree of bran and endosperm separation from the middlings?

A. I can't say specifically the wording of the order. I don't have a sample of that here, and I am not routinely

familiar with that. It is a matter of years since I have seen a written order on that.

Presiding Officer Willcox: Is that all?

Mr. Campbell: That is all.

Mr. Goodrich: That is all.

(Witness excused.)

1036A Whereupon

C. M. HARDENBERGH was recalled as a witness by and on behalf of the Industry, and, having been previously duly sworn, was examined and testified further as follows:

Mr. Campbell: Have you a statement to make with respect to farina?

The Witness: Yes.

Mr. Campbell: Mr. Hardenbergh has been sworn and has stated his qualifications and testified in this proceeding previously.

Direct Examination by Mr. Campbell.

Q. You will proceed, please.

A. We request that the same change in the wording in regard to this 10 percent by weight of durum wheat be made as was discussed and referred to in Section 15.000.

Mr. Goodrich: That was discussed by you?

The Witness: Yes.

We object to the use of this definition where you say "by grinding and bolting", just the same as we do to the description in connection with the manufacture of white flour. That is, we feel that from a technical point of view, a description of the manufacturing process is not necessary, and that the definition should read something along the line that farina is a food and consists of the
1037 cleaned endosperm of the wheat reduced to such fineness.

Q. Our attorneys request that a protest be made in regard to a description of the process. We recommend the ash limitation to be 0.5 of 1. percent, the same as yours.

We feel very strongly that the ash calculation should be made on a definite moisture basis, namely, 15 percent,

and should not be made on what is termed the "as-is" basis.

By Mr. Campbell:

Q. That is the reason you gave, when you were discussing Section 15.000?

A. Yes, and that has been discussed pretty fully, I guess, in connection with Section 15.000. I think there is no reason for going into that point. We simply want the record to show that we feel very strongly that the ash content should be related to a very definite moisture basis for calculation.

Paragraph (c) should be eliminated in connection with the changed previsions for durum wheat.

The request made for optional ingredients in connection with Section 15.000 we would like to have incorporated with this farina standard of identity. I will not enlarge on that as I think Mr. Gunderson's testimony went to that point, and this whole proposition of vitamins and minerals to be added to products of this kind is left open for
1038 further hearing on November 12th.

In connection with these allowances of the amount of material which can pass through a No. 100 sieve, practically all of the farina which is made by the mill and going to consumers, other than what the mills pack themselves in the form of farina as breakfast food, is made on specifications as to granulations.

The little information which the Federation has been able to pick up within the time allotted indicates that all of the farina when it is made, contains very little flour.

We have no criticism to make of the Government's testimony on that point. We agree with it.

On the other hand, we have had a little more experience in connection with the amount of flour which might be caused on account of abrasion in transit, and so forth, and we would like to see the figure set at 3. percent, which is the maximum suggested in this proposed identity.

Granular products, such as farina and semolina, are apt not to maintain their uniformity as to the granulations as they are shipped over the country. That is, it might easily be. If a sack of farina is handled pretty roughly and goes through the process of, what you might say, that you did it intentionally, jouncing it, you are going to get a different granulation in the bottom of the sack than in the top of the sack, and it might easily be
1039 said that farina which is shipped from the mill with almost no flour in it, that that would occur. It holds

particularly true of the softer varieties of farina, that is, farina made from softer varieties of wheat, that at destination the uniformity of your granulation has been so affected that if you took a sample out of one part of the sack, you would not get exactly the same granulation as if you took it out of some other part of the sack. We have had that complaint, and for that reason, we feel that a tolerance of 3. is not unreasonable and should be set rather than the 2.5 percent, as suggested by Mr. Callaway.

Small samples sent from a mill from Washington State to Washington, D. C., as far as the handling goes, might be subject to just as much abrasion as a carload shipment by freight; nevertheless, when the samples are tested, they are all uniform. You might say there isn't the chance in a small sample for one part to be a little different from the other. The samples are usually mixed before the test is made.

Do you get the idea?

Mr. Goodrich: Yes.

By Mr. Campbell:

Q. I have just one question, Mr. Hardenbergh. You stated that much of this farina is manufactured by the mills on specifications. Are those specifications
1040 made, for example, by firms who make up farina and sell it as a breakfast food and order it from the mills on certain specifications of their own?

A. Yes, both for repackers, and also macaroni manufacturers.

Presiding Officer Willcox: Off the record.

(Discussion off the record.)

The Witness: In connection with these optional ingredients with farina, there is, of course, no use in asking for bleaching as an optional ingredient, nor potassium bromate, as an optional ingredient, because these ingredients are not used in farina.

Mr. Campbell: At that point, I think it would be a good idea for me to make the same formal motion, that the record on Section 15.080, farina, be kept open and the hearing postponed until November 12th, on the same terms and conditions as in the case of Section 15.000.

Presiding Officer Willcox: If there is no objection, the same ruling will be made.

Mr. Goodrich: No objection.

By Mr. Vandenover:

Q. Mr. Hardenbergh, if farina were shipped long dis-

tances in transportation, and farina were packed on the one hand in packages, and it might be shipped in sacks on the other hand, you might find the grade in the sacks
1041 would be a great deal greater than if shipped in the package form? Wouldn't that be true?

In other words, it would not have the opportunity to have this juggling that might proceed from the facts, as you receive in the package form?

A. Yes; I can easily conceive that being the case, but we have no actual tests to that effect, particularly farina shipped by what they call lake-and-rail, for it has a good deal of handling in sacks. It is usually shipped in cotton sacks and it is pretty loose. You get a lot of jouncing, twisting up and down on it.

Presiding Officer Willcox: You haven't any tests which showed the amount of flour after shipment?

The Witness: No, we haven't any series of tests. We have had actual complaints from our customers to whom sales have been made on granulation specifications and they have claimed that the farina did not come up to the specifications, and upon investigation, it was proved and brought out, to their satisfaction, that their complaint was based on the not-complete-sampling of the farina; and when we demonstrated to them that had more samples been taken from the same bag and the product mixed, that the shipment was within the specifications.

Presiding Officer Willcox: Is that all?

(No response.)

1042 (Witness excused.)

Presiding Officer Willcox: Is there any further testimony in regard to farina?

(No response.)

Whereupon

EDNA VAN HORN was recalled as a witness by and on behalf of the consumers and, having been previously duly sworn, was examined, and testified further, as follows:

Mr. Goodrich: Miss Van Horn has been sworn and her testimony appears, together with her qualifications under Section 15.000.

The Witness: I would like to put our association on

record as in favor of paragraph 15.080, farina, as being a reasonable standard and definition of identity.

Mr. Goodrich: That is with the blanks filled as the Government has suggested that they be filled?

The Witness: Yes.

I think that is all.

Presiding Officer Willcox: Any cross examination of this witness?

(No response.)

Thank you, Miss Van Horn.

(Witness excused.)

Presiding Officer Willcox: We will now proceed 1043 with the whole wheat flour.

* * * * *

1194 Appearances:

Lowell Armstrong, 912 East Broadway, Louisville, Kentucky, appearing in behalf of Ballard & Ballard, 912 East Broadway, Louisville, Kentucky.

V. H. Engelhard, 912 East Broadway, Louisville, Kentucky, appearing in behalf of Ballard & Ballard, 912 East Broadway, Louisville, Kentucky.

1272 We as a company have been interested in the addition of other ingredients to flour, for a number of years. Vitamins, of course, have probably had more publicity than any of the other ingredients, and we, along with the other companies, have paid some attention to vitamin, let me say, publicity.

About a year and a half ago—and that is an approximate date—a representative of the Federal Health Department, the United States Public Health, or whatever the term is—and I am not sure of the term—visited with us thinking we could be of assistance to them in the injection or introduction of nicotinic acid into corn meal as a help in the control and preventing of pellagra in the South.

The Public Health Service had the idea we were millers of corn, but unfortunately we are not.

Nevertheless, that meeting or that visit from this Public Health representative gave us the idea there were probably other things we could do to flour that would be helpful to

the consumer and that would streamline our product,
1273 other than merely the addition of vitamins, which we had been thinking about before; the result of that visit was that Mr. Armstrong, who is with me here and who is our chief chemist, and I made a rather extensive trip into the East, visiting with the Merck Laboratories, the Fleischmann Yeast Laboratories, the Standard Brands Laboratories, and the Food and Drug Administration here. We wanted to discuss with the heads of those different laboratories the matter of vitamins, the matter of the introduction of health factors, and the matter of introduction of factors which would make our product meet the 1940 requirements better than we felt it was meeting them.

The result of that visit or those visits was, along with the research which was done by our own laboratory, and that is the Ballard Laboratory, led us to the conclusion, first, that calcium was a very vital part of the American diet and was deficient in the average American diet. That was our first conclusion.

I am giving you this historically, Mr. Campbell, because I think it is important, and it may be just a little long, but I will get to the point in a few minutes.

On our trip to Washington we tried to see Dr. Nelson and Dr. Elliott, but unfortunately we came here on
1274 Saturday and were unable to see them, but we did see Mr. Kneeland, who as I remember was at that time the assistant of Dr. Nelson, the administrative assistant, or something of that sort, I don't just remember the title.

At any rate, we went back very much sold on the idea—and this was not because of what Mr. Kneeland told us, but because of what we picked up,—we went back very much sold on the idea of the introduction of calcium into flour and the introduction of magnesium into flour to make the flour more usable.

And I might say here that later on we determined or our laboratory determined that the calcium we should use was calcium carbonate and the magnesium was magnesium carbonate. So when I speak of calcium, I speak of calcium carbonate and magnesium, the magnesium carbonate.

We felt after our visit here that the thing for us to do, and we still think we are right, was that before we did anything at all the proper procedure for us to take was to present to the Department and to Dr. Elliott in particular, our packages which contained the statements which we were to make.

We felt, in the first place, that we had a definite obligation to the consumer to make our product more
1275 usable, or let me put it this way, to make our product conform to the modern requirements or buying urges of modern American housewives. Those considerations are very simple, the health, the economy, and especially convenience. Family flour—and I think that I will state that our mill is primarily a family mill—family flour is not used at present to the extent it was used some years ago, very largely because of the difficulty of using it, the inconvenience of making a biscuit, the inconvenience of making a cake; and we felt that one of the important things for us to do was to make it easy for the consumer to make a biscuit; to make it easy for her to make a cake.

My grandmother had always started her Sunday dinner —and you have all had this experience—and my wife, our Sunday dinner usually starts when we get home from church, and if we don't happen to go to church, it still starts at half-past twelve. But with the modern living, we were trying to form a program with that trend in mind.

The calcium was obviously injected into our flour for its health value. I am not going to lay much stress on that, because Mr. Armstrong is very much more able to do that than I am.

1296 *Cross-Examination by Mr. Goodrich.*

Q. You are not a chemist, a pharmacologist, or a nutritionist?

A. I am just a plain, ordinary guy that tries to make an honest living.

Q. Do you know anything at all of the chemical characteristics of this flour, self-rising or Obelisk or whatever it is?

A. Except that the addition of calcium is helpful.

Q. You know that by hearsay?

A. That is right.

Q. Do you have any idea what the minimum daily requirement of calcium is, of the ordinary adult?

A. I should say—and it is on the package—750 milligrams.

Q. For how much?

A. For six and one-half ounces. That six and one-half ounces, the individual's particular consumption, of Obelisk

contains Obelite, 750 milligrams of calcium, which is the average daily requirement.

Q. This Obelisk flour would very rarely be the sole calcium-giving ingredient in an ordinary human's
1297 diet, would it not?

A. You mean they would not live on biscuits?

Q. Yes.

A. That is right.

Q. But you have undertaken to supply the entire minimum daily requirement?

A. That is right, because of the variation of the calcium intake and other foods. For instance if you drink a couple quarts of milk a day, you probably don't need the calcium in this product. But if you don't take enough calcium foods, you probably require a product of this sort. For mothers and children, and so on, it is very important.

Q. You say that you have undertaken to be helpful to the consumer by improving the public health, by adding these ingredients to your flour?

A. By adding the calcium, from a health standpoint, and by making the product easier to use.

Q. Then the only ingredient added from a nutritional standpoint, so far as you know, is the calcium carbonate?

A. Yes, except that if the product is easier to use, the nutritional value of flour, I think, is more acceptable to the consumer. Isn't that correct? I think
1298 that is a fair assumption.

* * * * *

1311 LOWELL ARMSTRONG, was called as a witness by and on behalf of Ballard & Ballard Company and, being first duly sworn, was examined and testified as follows:

Direct Examination by Mr. Campbell.

Q. State your name, residence, occupation and your qualifications to testify here, as a chemist, we will say.

A. Name—Lowell Armstrong; graduate of Purdue University, and hold a degree of Bachelor of Science in Agricultural Chemistry; employed two years as a Federal inspector at a canning factory, and approximately 10½ years as chemist for Ballard & Ballard Company.

* * * * *

1313 Let us first consider the calcium carbonate in relation to the four points named. I have here a record of a number of different baking tests which show that our self-rising flour containing the ingredients, calcium carbonate and magnesium carbonate bakes excellent biscuits at normal dough temperatures and that baking made from doughs at temperatures above normal, such as exists in practically all kitchens in the South for eight months out of the year, are superior to those from old types of self-rising flour.

Calcium carbonate has two definite functions as an ingredient of self-rising flour. The first, which we may term the health factor, and the most important, is the fact that it is a rich source of calcium and as such, makes possible the correction of the calcium-phosphorus ratio of self-rising flour.

The calcium-phosphorus ratio of self-rising flour is approximately 0.7. In our own flour, through the addition of calcium carbonate, we have a calcium-phosphorus ratio of 1. In support of this correction in relation of calcium to phosphorus, we cite Dr. Sherman of Columbia University, who states in his "Chemistry of Food and Nutrition" (Fifth Edition), page 292:

"Observations upon several species have indicated that during rapid growth and calcification, it is well that the
1314 food as a whole should have a calcium-phosphorus ratio somewhere between 1 and 2."

This means that growing children should have as much calcium as phosphorus in their diet, and it may be advisable to have as much as twice the quantity of calcium compared to phosphorus. He goes on to state that the relation of calcium to phosphorus can be somewhat lower in the adult, but that

"The calcium-phosphorus ratio of the whole body is a little under 2."

That is, nearly 2 calcium to 1 phosphorus.

Other investigators confirm Dr. Sherman's statements. Bethke, Kick & Wilder, working at the Ohio State University, report in the Journal of Biological Chemistry, 98, page 389 to 403:

"The most favorable calcium-phosphorus ratio for growth and bone formation was between 2 and 1."

That is, 2 calcium to 1 phosphorus. They also stated:

"When the calcium-phosphorus ratio was changed from 1 to 0.25, growth was depressed."

We have attempted to approach in Obelisk containing

obelite the optimum calcium-phosphorus ratio which has been placed at from 1 part calcium to 1 part phosphorus, to 2 parts calcium to 1 part phosphorus.

I might just explain that, when I say we have attempted to approach, I mean to say, we have a calcium-phos-
1315 phorus ratio of 1, but inasmuch as the optimum calcium-phosphorus ratio has been placed at from 1 to 2, we are only going as far as 1.

Have I made myself clear?

The correction of the calcium-phosphorus ratio with calcium carbonate provides in 6½ ounces of the flour approximately 750 milligrams of calcium, which amount has been taken as the average individual's minimum daily requirement.

In that connection, there are many figures available showing a minimum daily requirement, or possibly an average minimum daily requirement of 680 milligrams. I will give the authors and the quotations of that in a few moments. But our figure of 750 seems to be very nearly average.

Sherman points out that

"The intake of about one gram of calcium per day, which was found desirable for optimal retention, represents a desirable allowance to provide for individual differences."

The provision for large quantities of calcium in flour is especially important in the southeastern states, where white flour forms a very important part of the diet and where milk consumption is very low. We know that even among negroes where the diet is practically devoid of
1316 milk the use of our best flour is popular. Here a large proportion of the daily caloric requirement is obtained from biscuits made from white flour. For references on this point, we cite Circular 507, of the United States Department of Agriculture. I would like to read, if I may, a few of these—and, for the matter of the record, this is Circular No. 507, of the United States Department of Agriculture, entitled "Diets of Families of Employed Wage Earners and Clerical Workers in Cities," written by Hazel K. Stiebeling, and Esther F. Phipard. This is at page 49:

"Calcium and phosphorus are the chief inorganic substances entering into the skeletal structures of the body. They also serve other important functions. Calcium in small quantities is necessary in soft tissues and body fluids and, according to Peters and Van Slyke (34), organic and inorganic phosphorus compounds function in the body in

at least 14 ways. They play essential roles in intermediary metabolism as well as in building processes.

"Sherman concluded after a critical study of nearly 100 balance experiments on both calcium and phosphorus that the average minimum requirements for maintaining equilibrium were about 0.45 g of calcium and 0.88 g of phosphorus for a man of 70 kg of body weight. Diets of normal character but low in both nutrients were essential features of these studies.

"The utilization of both calcium and phosphorus is influenced by a number of factors, including the ratio which they bear to each other, the quantity of vitamin D supplied by sunlight or food, and the quantity of fat in the diet. To allow for the variation likely to be encountered in everyday foods, and to safeguard those persons whose requirements are higher than average, a 50 percent margin has been added to average minimum requirements in formulating dietary allowances. These additions bring the allowances for acceptable diets to 0.68 g of calcium and 1.32 g of phosphorus a man a day.

"Certain physiological conditions increase the relative requirements for these minerals. An abundance is needed for growth in infancy and childhood, and to cover the increased requirements of women during pregnancy and lactation.

"Extensive studies of the mineral metabolism of children indicate that an intake of a gram each of calcium and of phosphorus for a child each day results in good retentions when other factors are favorable. In this country, these quantities have been generally accepted as an adequate allowance for both calcium and phosphorus in diets of children. Extra calcium, enough to bring the daily intake to at least 1 g a day, should be provided for women in pregnancy and lactation.

"In a recent evaluation of the data now available, Leitch concludes that minimum gross requirements for calcium are as follows: From 6 months to 2 years, 0.8 g; from 2 to 9 years, 0.9 g; from 9 years, 1 g increasing to 2 g between 15 and 16 years; thereafter a gradual decrease to the adult maintenance requirement, which she believes to be about 0.55 g daily.

"The League of Nations' Technical Commission on Nutrition recommends that diets for men of 70 kg body weight should supply about ¾ of a gram of calcium daily, for

pregnant and nursing women about 1½ g, and, apart from breast-fed babies, for growing children, about 1 g daily. In most diets of natural food materials, phosphorus will be supplied in sufficient quantities when calcium is adequately provided."

In Table No. XXX appearing on page 50 of this publication, a system was worked out here which was used in making a survey of the calcium intake of families and different food expenditure levels in various sections of the United States. And because of the fact that the composition of these families would always be of a different nature,

that is, there would be a man in one family and the
1319 wife, and say, two children, whereas in the other one

there would be a man and three children and the wife; and since the requirements of each of those individuals are different, they set up what they call a "requirement unit," representing 680 milligrams of calcium per day.

I don't know whether it is in order in this procedure to ask questions, but if I don't make myself clear in the explanation of this table, which is rather confusing, I would like to invite questions.

In this survey, the food expenditure level of 63 cents to $1.24 per person per week, gave a calcium intake of 410 milligrams for each requirement unit, that is, where they should have received 680 milligrams, they received 410.

The negros who spent the same amount of money in the South, received 330 milligrams, whereas they should have received 680.

All of these figures are per requirement units taken as 680 milligrams.

The same thing holds true for the group that spent $1.25 to $1.87 per person per week. In this particular case, the negro in the South received 540 milligrams, as against an average of 450 milligrams for the white people. In that particular case, the negro was better fed than the white people.

1320 In the next group representing a food expenditure of $1.88 to $2.49, the calcium intake was 540 for the North-Atlantic, ranging all the way on up to 670 or 680 for some of the individuals in that group.

In other words, when they reached this level of food expenditure, they had practically sufficient calcium intake.

I bring these figures to your attention because of the fact that these localities represented here are localities

in which self-rising flour, at present, is being used. And the calcium intake of those families was as high as it is because of the liberal use of self-rising flour.

And despite this use of self-rising flour, in many cases the calcium intake was only half what it should have been.

In summary of this, I think that we can read this hurriedly here:

"In general, the average calcium and phosphorus content of the diets increased with rising expenditures for food. At each food-spending level, the averages for the different regional groups show some variability, but those for the families in the South are definitely higher than others, especially at the lower expenditure levels. Figures
1321 for the calcium and phosphorus in the food of families in the South take into account the quantities contributed by self-rising flour."

And even where those figures are taken into consideration, they are still low.

In regard to the calcium requirements and the function of lime salts in the human system, I want to read the following from the Dispensatory of the United States, Centennial Edition, 1937.

Mr. Callaway: You mean the United States Dispensatory?

The Witness: However it is named. It makes no difference to me. That is the way it appears on the frontispiece.

Mr. Callaway: It is not a government publication?

The Witness: That is satisfactory.

Mr. Goodrich: Yes.

The Witness: (Citing) Calcium, page 261:

"This is the metallic constituent of lime and consequently of all calcareous substances.

"Calcium is a very abundant element in nature, existing in the mineral kingdom chiefly as a carbonate in the form of limestone, marble, chalk, and so forth.

"Therapeutic action:

"The normal function of bodily organs, muscular,
1322 glandular, or nervous, is conditioned on the proper relation between codium, potassium and calcium. Any disturbance in the balance of these metals leads to alterations of cellular activity, or if the disturbances be great enough, death of the part. The blood normally contains about 11 milligrams of calcium per 100 c.c., but in

what form the metal is present is unknown; presumably a part of it exists in a colloidal suspension . . . . ".

"We may point out that the amount of calcium in the body depends upon at least four factors, namely the calcium intake, the phosphorus intake, the activity of the parathyroid gland, and the amount of Vitamin D . . . "

"Although a number of investigations as Dennis and Minot (Journal of Biological Chemistry, 1920 XLI 357) have been unable to demonstrate an increase in the blood-calcium in human beings from the ingestion of lime salts, that such increase is possible seems to us completely established, not only by the therapeutic effects of lime salts, but also directly by the studies of Lieberman (Journal of Pharmacology and Experimental Therapeutics 1931 XLII 245) and many other investigations . . . . "

"It may be remarked that the amount of lime salt which
1323 is required to produce measurable increase of the blood calcium is much larger than has sometimes been used medicinally. Practically all authorities agree that an amount of the salt equivalent to about 0.4 gram of elemental calcium is required." (This equals 1 gram $CaCO_3$).

In terms of calcium carbonate, that would be one gram.

"There is a marked effect of lime salts upon the heart when injected into the blood stream," (increases the contractile power of the heart muscle; but we are not interested in this since our product is taken orally).

"A very interesting pharmacologic effect of calcium is that exerted on certain inflammatory processes."

There is an explanation of that which I don't think is pertinent here. Again:

"Calcium is essential for many of the bodily enzymic actions, notably that involved in the coagulation of the blood.

"As a practical therapeutic agent calcium has been used for a large variety of conditions. In the convulsive disorder of children known as tetany which is by many regarded as due to deficiency of parathyroid hormone, it frequently causes a temporary improvement."

Those experiments on that are reported by Shohl &
1324 Wolbach, in Journal of Nutrition in 1936, and the title is the "Effect of Low Calcium Duets on Tetany."

Then, "Tweddell, in the New York Medical Record, and others, state that among those whose occupations brings

them in contact with the dust of lime or its salts, tuberculosis is almost unknown and several writers have recommended Calcium salts in the treatment of pulmonary and intestinal tuberculosis. Grand, in the American Review of Tuberculosis, June, 1930, found that rats kept on a diet deficient in calcium and Vitamin D were abnormally susceptible to tuberculosis infection.

Fishberg in the Journal of the American Medical Association, 1919, reports marked benefit from the use of lime salts in the diet in the early stages of tuberculosis enteritis before extensive ulceration has set in. In advanced stages of this disease, the lime salts exert little effect.

"Concerning the clinical value of lime salts in hemorrhage, there has been so much difference of opinion that it is impossible to draw positive conclusions."

Summarizing these references in regard to the requirement of calcium, we have shown that calcium is essential and that in order to provide for individual differences at least 1000 milligrams should be ingested daily.

1325 Of this amount in families where the flour consumption runs as high as 6½ ounces or 13 liberal-sized biscuits, we supply ⅞ of this maximum amount.

That is the end of the quotations.

1333 *Cross-Examination by Mr. Goodrich.*

Q. Mr. Armstrong, you cannot testify as a nutritionist, a pharmacologist, or a medical doctor, can you?

A. I cannot qualify as a pharmacologist nor as a medical doctor. I have had, of course, the ordinary courses in biological chemistry in regard to nutrition.

Q. You have made no special study of nutrition and the demands of the human for nutrients?

A. No, sir.

Q. There appears in Sherman's book entitled "Chemistry of Food and Nutrition," 1937, Fifth Edition, from which you have quoted on page 520, a statement of the standards for calcium, phosphorus, and iron content of the dietary.

In the second paragraph of that section, it is stated that

"If the standard allowance be set 30 percent above
1334 the indicated average minimum, we obtain as allowances for adult maintenanuce: Calcium 0.68 gram; Phosphorus, 1.32 grams."

Is that in accordance with the other material which yo
read from the book, stating the calcium-phosphorus ra
tions should be two parts of calcium to one part of phos
phorus; or one part of calcium to one part of phosphorus

A. There is a difference, Mr. Goodrich, between the
ratio as expressed there and the optimum ratio which I
read to you.

I might call your attention to the wording here. It says:
"We obtain as allowances for adult maintenance"—
making no mention of optimum ratios.

Q. Then this is the standard for the average intake?

A. As I understand this reference you are reading
this has been allowed as a standard for adult maintenance
with no mention being made of whether or not it is op
timum, or whether or not better health would result as the
result of larger intakes of calcium.

Q. But these standards are set up for use by Dr. Sher
man, with the recommendation that when supplied in that
amount, the minimum will be contained in sufficient
1335 quantities in the dietary.

A. For the adult, yes.

Q. There is also a statement there, I believe, you need
make no difference between the adult and the child, is there
not, on page 521?

A. To continue reading, if I may, here, for the record,
this is from "Chemistry of Food and Nutrition" by Dr.
Sherman:

"Because of the increased demands for calcium during
growth, pregnancy, and lactation, the maintenance allow
ance for calcium suggested above cannot be considered
adequate for children or for women during the reproduc
tive period. Studies of calcium and phosphorus metabolism
in children have indicated a requirement of about 1 gram
each of calcium and of phosphorus per day for the growing
child. These findings furnish us additional reason for con
sidering the child separately from the adult in planning
the family dietary. But it should also be kept in mind that
for the family as a whole better permanent results may
be expected when the calcium intake is higher than this
conventional standard allowance. It is doubtless better
for the family food supplies to furnish at least 1 gram of
calcium per capita per day."

1336 Q. But the ratio, nevertheless, is stated here to
be less for calcium than for phosphorus in the stand
ard dietary?

A. That is right.

Q. Then your ratio is for special circumstances, the growing child or the mother during the period of child bearing, or period of lactation?

A. Will you state your question again, please, sir?

Q. The ratio of calcium to phosphorus of 1-to-1 is a ratio which is especially provided for women during the child-bearing period and during lactation, and for the growing child, rather than from the family point of view, as a whole, is it not?

A. The reference that I made to Sherman, Fifth Edition, page 292, refers to the calcium phosphorus ratio during rapid growth; yes, sir.

Q. Does Vitamin D have any effect during this period, in this connection?

A. Yes, sir.

Q. And that is not supplied in your flour?

A. No, sir; we are depending upon the sunshine of the South.

1367 BEFORE THE ADMINISTRATOR, FEDERAL SECURITY AGENCY.

In the Matter of a Definition and Standard of Identity for Each of the Following Foods:
(A) Flour, White Flour, Wheat Flour, Plain Flour; (B) Durum Flour; (C) Whole Wheat Flour, Graham Flour, Entire Wheat Flour; (D) Cracked Wheat; (E) Crushed Wheat; (F) Whole Durum Wheat Flour; (G) Self-Rising Flour, Self-Rising White Flour, Self-Rising Wheat Flour; (H) Phosphated Flour, Phosphated White Flour, Phosphated Wheat Flour; (I) Farina; and (J) Semolina.

Docket No. F. D. C. 21.

Place—Washington, D. C.

Date—November 12, 1940.

Room—3106, South Building, Department—Agriculture, Washington, D. C.

The above-entitled matter was resumed at 10:00 o'clock a. m. before the Administrator, Federal Security Agency.

Alanson W. Willcox (Presiding).

Appearances:

As heretofore noted.

Appearances:

Lowell Armstrong, 912 Ea. Broadway, Louisville, Kentucky, appearing on behalf of Ballard & Ballard Company;

Dudley Browne, 850 Munsey Bldg., Washington, D. C., appearing on behalf of General Biochemicals, Inc.;

Daniel M. Dent, 350 Madison Ave., New York, N. Y., appearing on behalf of The Borden Company;

V. H. Engelhard, 912 East Broadway, Louisville, Kentucky, appearing on behalf of Ballard & Ballard Company;

Dr. Charles N. Frey, 595 Madison Ave., New York, N. Y., appearing on behalf of the Fleischmann Company, and Standard Brands, Inc.;

Paul R. Frohring, Chagrin Falls, Ohio, appearing on behalf of General Biochemicals, Inc.;

James M. Gillet, 1724 Chancellor Street, Evanston, Illinois, appearing on behalf of Victor Chemical Works;

Prof. Robert S. Harris, Massachusetts Institute of Technology, Cambridge, Mass., appearing on behalf of the Cream of Wheat Corporation;

Dr. R. E. Lee, 595 Madison Avenue, New York City, appearing on behalf of Standard Brands, Inc.;

M. A. Lehman, 2712 W. 40th Street, Minneapolis, Minnesota, appearing on behalf of the Millers' Federation;

Whitman Rice, 129 Front Street, New York City, appearing on behalf of the National Sugar Refining Company;

James R. Scully, 17 East 42nd Street, New York, N. Y., appearing on behalf of Commercial Solvents Corporation;

W. H. Strowd, 603 Exchange Bldg., Nashville, Tennessee, appearing on behalf of the National Soft Wheat Millers Association;

Robert E. Waterman, Spring Valley Road, Morristown, New Jersey, appearing on behalf of the Research Corporation, 405 Lexington Ave., New York, N. Y.

1368 Proceedings.

Presiding Officer Willcox: The hearing will please come to order.

As most of you know, this is an adjourned hearing on the proceedings looking forward to the establishment of definitions and standards of identity for flour and other wheat products. The primary purpose of this adjourned hearing is to take further testimony on the subject of the addition of vitamins and certain minerals to flour and other products.

1374 C. M. HARDENBERGH, was recalled as a witness by and on behalf of the Industry, and having been previously duly sworn, was examined, and testified further, as follows:

Direct Examination.

By Mr. Campbell:

Q. Mr. Hardenberg, you have testified before and been sworn as a witness in this proceeding, have you?

A. Yes.

1375 Q. Directing your remarks to the question for which this hearing was postponed, that is, for an addition of vitamins and minerals in various flours, have you a statement you would like to make?

A. Yes.

Q. Will you proceed and make that statement?

A. At the previous hearing in the matter of establishing definitions and standards for flour and other flour mill products, the Millers' National Federation proposed that a number of nutritive ingredients be added to the proposed definitions as optional ingredients.

It was our opinion at that time that it would serve the best interests of the consumer, the industry and the Government to provide a satisfactory procedure by which vitamins and minerals might be added to flour.

The Government in turn proposed that a separate standard be set up for such a flour to which might be added any one or all of a number of vitamins and minerals, at the option of the miller, and that the flour product so prepared should be called by a distinctive name, such as "Enriched Flour."

The milling industry has given this problem very serious consideration. The Federation has conducted a series of regional meetings of millers throughout the country at which the views of the millers were developed.

1376 Representatives of the industry and the Federation participated in conferences with leaders in the scientific field of nutrition and with Government officials.

These conferences were followed by a meeting of the Executive Committee of the Federation at which meeting a Federation and industry policy was outlined.

It was the consensus of the Executive Committee that the industry should cooperate wholeheartedly with nutritionists and the Government in developing and promoting a product which will better meet the nutritional needs of the consumer.

It is my purpose to present that policy at this hearing in the form of a proposal, together with our reasons for making the proposal in the form in which it will be presented. We shall also present several witnesses who will testify as to the technical, scientific and nutritional phase of the proposal, and especially as to the practical commercial problems involved.

The milling industry is conscious of the fact that for many years nutritionists have been advocating a wider consumption of Whole Wheat Flour. The milling industry has made these Whole Wheat Flours available to the consumer. In spite of all the efforts that have been made in this direction, less than 2 percent of the total Wheat Flour production of the country is Whole Wheat
1377 Flour. This demonstrates that the consumer will not eat Whole Wheat Flour as a steady diet.

Until quite recently, nutritionists were not in position to tell us just what there is in the Wheat Berry that makes it nutritionally desirable aside from its well-known properties, namely, carbohydrates and proteins. Modern scientific and nutritional studies have developed facts indicating that wheat contains a number of vitamins and minerals which are essential to the maintenance of normal good health. We find, however, that these elements are contained in wheat in varying amounts. The amount contained in the same kind of wheat will vary from year to year. The amount contained in different kinds of wheat, that is, hard spring, hard winder, and soft winter, vary materially. We find also that these elements are usually found in increasing amounts as we analyze the Wheat Berry from the center of the endosperm to the outer bran coatings. One of our problems, therefore, is how these nutritive elements of the Wheat Berry may be most effectively made available in a flour which will appeal to the consumer.

Dr. C. H. Bailey, of the University of Minnesota, will describe in detail the composition of the Wheat Berry and testify as to the availability of its nutritional properties

and the difficulties of their retention in the manufac-
1378 ture of a satisfactory flour.

The milling industry recognizes the desirability of meeting the demand for better nutrition, and we desire to prepare ourselves to meet this demand. However, it must be recognized that the industry has some very practical commercial problems confronting it which must be solved whether we retain these nutrients so far as possible in the milling process or add nutrients to our flours.

In our proposal we are attempting to define a product which is not yet generally produced on a commercial scale. The manufacture of longer extraction flours which will retain to a greater extent the nutrient elements desired will require more grinding and bolting operations and thus add to the production expense. Inasmuch as we believe it is impossible to produce a satisfactory flour which will retain all the nutrient elements at the levels which we understand are being advocated by eminent nutritionists, it will be necessary in most instances to supplement these natural sources with synthetic nutrients. This will add to the cost. This additional cost will vary, depending upon the extent to which the natural nutrients are retained and the extent to which the nutrients from outside sources must be added.

It must be recognized that the more nutrients required to bring the flour to the recommended levels, the
1379 greater the cost at present prices of these added nutrients.

The industry believes, based on its past experience, that there will be a greater consumer preference for the shorter extraction flours in which the nutrients have been enhanced by addition to meet a definite standard.

One of the most difficult problems will be that of analysis and assay of the finished product to determine whether or not the required levels are present. This will involve installation of expensive analytical equipment and the employment of skilled analysts. This is such a new field, that it is generally recognized that unavoidable differences in results will be obtained even by competent analysts employing the same equipment and standardized technique. At the present time there is no recognized standard technique for some of the nutrients being considered. Allowance will have to be made by Food and Drug Officials in administering the standard for the differences which will

inevitably occur in making the determinations with the existing available methods.

We believe our proposal is also in the interest of the wheat producer of the United States. Since 1900, the per capita consumption of wheat as flour has declined from 225 pounds to 154 pounds, as indicated by data compiled by the Food Research Institute at Stanford University.

If the level of per capita consumption of 1900
1380 could have been maintained, we would be consuming today approximately 200,000,000 bushels of wheat more than we are consuming at the present time. We think it is fair to assume that by making available in wheat products more of the nutritional elements natural to wheat, an increased consumption of wheat in the form of flour to the benefit of the consumer and the wheat producer alike will result.

We recognize that flours of this kind in order to provide the consumer with a level of nutrition which can be regarded as completely satisfactory should not only contain the nutrients necessary for this purpose, but also minimum and maximum levels should be specified in the standard. In our proposal, it is provided that the product shall contain Vitamin B_1 and that in addition it may contain, at the option of the manufacturer, riboflavin, nicotinic acid and Vitamin D, and the mineral elements calcium and iron. We have not proposed specific levels. We anticipated that the nutrition experts, including these in the Government, will arrive at and recommend specific levels.

In addition, there may be other optional ingredients suggested by the Government or nutritionists or other interested parties.

Our proposal does not contain specific minimum or maximum levels. We believe there must be some
1381 minimum and maximum provided on a rational rather than on a fanciful basis. This suggests the thought that the minimum should be sufficient to afford a significant dietary contribution and that the maximum might be the average high level of Whole Wheat which would be comprehensible to the public. We believe such levels would promote honesty and fair dealing in the interests of the consumer.

We wish to emphasize the fact that we are entering a new field in which we must necessarily have to depend upon scientific data available today. We are proposing a stand-

ard of identity for a special flour which will call for a nutritional standard based upon a recognized nutritional property of wheat to meet a recognized nutritional need.

Such a flour, whether meeting the B, requirement alone or including any one or all of the optional nutrients, must give baking satisfaction under conditions of both home and commercial use.

Undoubtedly, continuous progress will be made in the science of nutrition. We present this proposal on the basis of nutritional knowledge as it exists today, with the distinct recognition on our part that as science develops new information and new data, it may be necessary to amend and modify the standard to conform to the latest available knowledge.

Q. Now, Mr. Hardenbergh, has the Millers' National Federation Committee drafted a proposed standard of identity which it would like to submit at this time for the record?

1382

A. Yes.

Q. Will you please read that proposed standard of identity?

A. The proposed standard of identity which we have labeled "15300 Vimin Flour, identity, label statement of optional ingredients.

(a) Vimin Flour is the fine ground product of cleaned wheat, except durum, prepared to provide essential nutritive elements in amounts hereinafter specified. Such proportions of malted wheat and/or malted wheat flour may be used as compensates for any natural deficiency of enzymes. Its moisture content is not more than 15 percent. Unless such addition conceals damage or inferiority of the flour or makes it appear better or of greater value than it is, one or any combination of two or more of the following optional bleaching ingredients may be added in a quantity not more than sufficient for bleaching, or in case such ingredient has an artificial aging effect, in a quantity not more than sufficient for bleaching and such artificial aging effect.

1383

1. Oxides of nitrogen.
2. Chlorine.
3. Nitrosyl chloride.
4. Nitrogen trichloride.
5. Benzoyl perozide, added as a component of a mixture containing not less than 15 percent of benzoyl pero-

zide and not more than 5 percent of magnesium carbonate, the remainder of such mixture being calcium sulphate.

(b) When any optional bleaching ingredient is used, the label shall bear the word "Bleached." Whenever the name "Vimin Flour" appears on the label so conspicuously as to be easily seen under customary conditions of purchase, such word shall immediately and conspicuously precede or follow such name, without intervening written, printed, or graphic matter, unless the word "Flour" is part of a previously registered or established trademark, in which case the name "Vimin Flour" shall again appear on the label so conspicuously as to be easily seen under customary conditions of purchase, with the word "Bleached" immediately preceding or following such name without intervening written, printed, or graphic matter.

(c) For the purpose of this section:

1. Moister content is determined by the method pre-
scribed in the book "Official and Tentative Method of
1384 Analysis of the Association of Official Agricultural
Chemists," Fourth Edition, 1935, page 206, under "Vacuum Oven Method—Official."

(d) Not to exceed ¼ of 1 percent of malted barley and/or malted barley flour may be used as compensates for any natural deficiency of enzymes. When such malted barley and/or malted barley flour is used the label shall bear a plain and conspicuous declaration of that fact.

(e) It shall contain:

1. Not less than ____ mg. nor more than ____ mg. of Vitamin B_1 (Thiamin hydrochloride) per pound.

(f) It may also contain one or more of the following optional ingredients:

1. Not less than ____ mg. nor more than ____ mg. of riboflavin (or its equivalent in riboflavin concentrate) per pound.

2. Not less than ____ mg. nor more than ____ mg. of nicotinic acid (or nicotinic acide amide) per pound.

3. Not less than ____ units nor more than ____ units of Vitamin D per pound.

4. Not less than ____ mg. nor more than ____ mg. of
iron (as Fe) per pound in the form of its assimilable
1385 salts.

5. Not less than ____ mg. nor more than ____ mg.

of calcium (as Ca) per pound in the form of its assimilable salts.

The required and optional nutritive ingredients may be supplied by the addition of vitamins in purified form and/or in acceptable concentrates, obtained either from natural sources or by adding synthetics. When any vitamin or mineral added in conformity with this section (15.010) is in the form of a concentrate, it may be accompanied by any other vitamins and minerals naturally present in the concentrate.

Q. Mr. Hardenbergh, in your general statement in regard to vitamins in flour, and the suggestion that a separate standard of identity be established for a flour containing minimum amounts of specified nutrients, you refer to this flour as "Vimin Flour."

Why has the Federation suggested this name?

A. There has been considerable discussion among the millers in regard to a suitable name for this "Vimin Flour." The industry does not like the adjectives "enriched" or "restored" because either one casts an unwarranted stigma on the flour which is now being made and which the mills must continue to offer to the consumer. It must be recognized that while the special flour under
1386 consideration may prove to be a benefit to a considerable portion of the consuming public, particularly the lower income group, there will still be a large number of consumers who will not be particularly benefited by using this flour, and we feel that no term should be used in connection with this special flour which would lead these consumers to believe that "flour", "white flour", "wheat flour," "plain flour" is not just as good as it ever was.

The term "Vimin" was chosen to designate this particular type of flour because it is intended that both vitamins and minerals will be comprised within it either as requirements or as optional ingredients.

At the present time it is proposed that only Vitamin B_1 shall be designated as a requirement, and that other vitamins and the minerals calcium and iron be included as optional ingredients. As consumer acceptance of this type of flour increases, it is probable that some of the vitamins and minerals named as optional ingredients will in the course of time become requirements within the standard of identity. It is thought that the name "Vimin"—which is a contraction of the terms vitamin and mineral—if

adopted at this time will be sufficiently descriptive to cover these changing conditions.

Secondly, the industry, based upon its experience
1387 in the marketing of flour to the housewife, knows that without question it would be much easier to educate the consuming public to use this flour if it is given a short, simple, easily pronounced name such as "Vimin" rather than any longer term that might be perhaps more accurately descriptive but cumbersome.

We believe that the dissemination of information in regard to a flour of this kind is going to be a very important factor in building up and establishing the consumer acceptance of it and we can not urge too strongly the use of a simple, easily pronounced name and believe that "Vimin" will answer the purpose better than any other names which have been suggested.

Q. Mr. Hardenbergh, why do you recommend Vitamin B_1 (thiamin) as the only required nutritive element in your proposal for a standard of identity and suggest that other vitamins and minerals be named as optional ingredients?

A. It is our understanding that of all the supplemental nutrients we are discussing, by far the most important is B_1 (thiamin). On view of the fact that it is well-known that wheat is an excellent source of B_1, it is logical that the industry sponsor a program of this kind with particular emphasis upon B_1. Therefore, we have proposed a definition of identity for this special "Vimin Flour" with B_1
1388 only as a requirement and the others as optional.

The nutrient factors other than thiamin should be listed as optional ingredients to permit manufacture of such flour for sectional or limited consumer use.

Methods of analysis are inadequate at the present time to insure uniform levels of some of these optional ingredients.

The cost of fortification with all of these nutrients might be so appreciable that it would tend to interfere with widespread purchase and use.

B_1 will serve the most general immediate nutritional need, is most readily available and will facilitate the most prompt inauguration of the nutritional program on an industry-wide basis. Its control and regulation are relatively less complex and will thus promote honesty and fair dealing in the interest of consumers.

Mr. Campbell: That is all we have.

Mr. Goodrich: If anyone else cares to cross examine, they may go ahead. I want to look over my notes at present.

Presiding Officer Willcox: Are there any questions of Mr. Hardenbergh from other than Government's counsel?

Mr. Rice: How is that name of the flour spelled?

1389 Mr. Campbell: Vimin, V-i-m-i-n.

Presiding Officer Willcox: Mr. Hardenbergh, did your proposal include any requirements of label statements for these ingredients other than Vitamin B_1?

The Witness: We assume if they are optional ingredients, under the name "Vimin Flour", they will have to carry label statements.

Presiding Officer Willcox: All right, Mr. Goodrich.

Cross-Examination.

By Mr. Goodrich:

Q. Your industry is definitely opposed to the policy of building the flour up to, say, an 85 percent extraction of flour without adding these nutrients?

A. The industry feels that if a program of this kind is inaugurated, it must carry minimum levels, that is, of B_1 and these other ingredients as optional ingredients, which minimum levels will be sufficient to do some good. Otherwise, there is no point in the program at all.

Just exactly what these minimum levels are, the milling industry at this time is not ready to state. We perhaps may be able to make a definite recommendation before the close of the meeting, because you appreciate there are going to be some other meetings. Therefore, to say

1390 that the industry is opposed to making a long extraction flour without additional vitamins, that question could not be answered until the minimum levels are established.

Q. I had in mind your statement that there are manufacturing difficulties in preparing a long extraction flour, and that consumer acceptance of that type of flour would have to be built up and the building up of that acceptance would be most difficult.

A. We feel that the consumer will prefer a shorter extraction flour built up to levels which will do some good, rather than a flour of such long extraction that it meets these levels, if it is possible to meet them in the long extraction.

We don't know what the levels are so I will have to qualify that statement a bit.

Q. Now, you stated that you think that the minimum and maximum levels in the standard should be on a rational basis and that the addition should make some substantial contribution to the American Dietary and that the maximum should be a high average level for the Whole Wheat Berry.

In that formula, you have not considered the daily requirements of the persons likely to consume this Vimin flour, as you have called it?

1391 A. There are going to be expert nutritionists and Dr. Bailey, who is going to testify for the millers in connection with the practical milling end of this question later on, and I would rather leave to the experts this question of daily intake, and so forth.

Q. I was directing my attention to what would be a substantial contribution to the Dietary under the high average of Whole Wheat. If you have any figures on that, or if you would rather reserve that until a later time—

A. I would rather reserve that until a later time.

Q. On your label declaration of the name "Vimin Flour", are we to understand that you treat "Vimin Flour" substantially as we treated "Bleached Flour" at the last hearing?

Where, for instance, the Commander Larrabee Company has an established trade mark for a flour label, you would add the name "Vimin Flour" and leave the trade mark on there with the word "Flour" in the existing mark?

A. That is correct; if the word "Flour" could not be taken out without destroying the label, it would be left in and then "Vimin Flour" would be shown very prominently.

It is our idea that the mills would probably have to change their brands somewhat in order to make it clear that this is Vimin Flour.

1392 For instance, I can recall one brand of flour in which there is a certain name, and the word "Flour"; and in that brand the word "Flour" could be eliminated and "Vimin Flour" placed below.

If you have a brand, however, which reads "Smith's Flour" and it is so made up and so constituted that it would affect the registration of the trade mark to take out that name "Flour," that "Flour" might be left there if the word "Vimin Flour" could appear very promi-

nently below that, so it can be seen that it is "Vimin Flour."

Mr. Campbell: Mr. Presiding Officer, perhaps I overlooked making a statement in connection with this proposed definition.

Under the Rules of Procedure, where a separate standard of identity is being discussed and is in issue, the testimony with respect to that standard should be complete in itself, so perhaps I had better make a motion that the testimony of the Millers' National Federation with respect to these bleaching ingredients and the position of the term "bleached" on the label which we introduced under Section 15.000, should be incorporated in the testimony under this standard of identity.

Presiding Officer Willcox: I don't think there could be any objection to that at this time, Mr. Campbell.

Mr. Goodrich: I think I would state for the record
1393 that the original notice is considered sufficient to this, and any testimony that comes in under "Flour" where it results in one or two standards, is all relevant to the original proposal for this will all be in the record in which is now the bleaching testimony; but there is no objection to your stating this in this connection.

Mr. Campbell: Yes, I will adopt your statement.

By Mr. Goodrich:

Q. Is it your idea that the use of the word "Vimin Flour" in connection with the existing trade marks, will have any substantial effect on the merchandising program through which you hope to get this Vimin Flour into the market, the idea being if you sold it under your existing trade mark, the consumers would not notice any substantial difference between that flour and the other flour if you used the same trade mark?

It seemed to me it probably would be better to eliminate this part of the proposal and have all the representations to be in the name of Vimin Flour, if that name finally is adopted.

What is your idea on that?

A. I don't think the mills want to get away from the individuality of being able to market their own prod-
ucts.

1394 Q. I understand that, but I mean if they start selling Vimin Flour, it seems to me each mill should adopt some way of merchandising Vimin Flour as they

chose, and not tie it into their existing merchandising program.

A. Well, you understand that my answer to that is only my personal opinion. I can't speak as a representative of the industry.

Q. Yes.

A. I am quite sure that if you take some of the best recognized brands of family flour—I am talking about the housewife; I am not talking about bakery consumption—if you take the best and most established brands of the mills that are on the market today, and you put on that established brand—take Pillsbury's or Gold Medal because they are the two leading family brands on the market today—and put on there "Vimin Flour" where it can be seen, if those milling companies get behind Vimin Flour with the help of the nutritionists of the country and the Government whatever that may be, I think you will have much more flour consumed by the housewife than if you tried to discard the name of Pillsbury's and Gold Medal and discarded Commander Larrabee and Russell Miller's brand, and they would have to pick out of the air a name and call it "_____"—just call it "_____ Vimin Flour."

Q. I would not have any idea of discarding those 1395 names. My idea is instead of "Pillsbury's Best Flour" and under that "Vimin Flour," that you have "Pillsbury's Vimin Flour" or something of that kind.

A. As I stated, where that can be done that is eliminating the word "Flour" and saying "Pillsbury's Vimin Flour." I think that is the natural thing for them to do, providing the elimination does not mean reregistering trade marks and everything. I think that is a detail, rather than an important point.

Q. In paragraph F of sub-section (f) of your proposed Section 15.010, it is stated that a certain amount of riboflavin be added as an optional ingredient, and it is provided that the equivalent of the riboflavin may be added in the form of riboflavin concentrate.

Would you care to make any statement on that, or do you want to leave that until later for some of the other men who follow you?

A. Other than to simply state that it is my understanding that the riboflavin in the pure form is so damned expensive and hard to get that you couldn't get it right

now—beyond that I will leave it to the technical men to take that up.

Q. I guess the same statement would apply to any concentrates which you have suggested here, say, on page 3 of your proposal?

1396 A. Oh, no; that would not apply to all of them.

Shall I tell you what they told me? You can ask the technical men—I would just as soon leave it to the technical men.

Q. In your proposal, it is stated that this Vimin Flour shall be the clean ground flour of wheat other than durum wheat. In our original proposal we suggested other than durum or red durum. Do you intend to exclude red durum from this?

A. Yes.

Q. And as a carrier for benzoyl peroxide as a bleaching agent, there was evidence at the original hearing that at least one company puts out a benzoyl peroxide in a carrier of potassium aluminum sulphate with a certain amount of water crystallization. Was that intentional or inadvertent?

A. It was not intentional.

Q. In your flour, there is no provision for the removal of the bran or germ except the fine ground product of clean wheat. Do you consider that any required degree of purification or separation from bran coat and germ is necessary in this type of flour and if so, what is that degree and how would it be measured?

A. I think there would be a natural separation because if there were no separation by bolting, you would
1397 have whole wheat flour.

It is impossible for us to set a definite dividing line until we are able from the information which will be introduced, to determine some of these minimum limits as to just what this extraction has to be.

Q. Extraction, or would you tie it in with the ash limitation on the flour, plus the ash coming from the required or optional ingredients included in your Vimin Flour?

A. Dr. Bailey is going to introduce some evidence later in connection with the relationship—not the relationship, but in connection with the ash content and the nutritive elements in these longer extraction flours. And, while your question is very much to the point, I think it is something that is difficult to answer at this time, because what

we are trying to do is establish a standard of identity for a flour or flours which we believe will help this whole movement, rather than to try and be terribly specific as to just exactly where the thing will cut off as to ash. We don't know.

Q. From your testimony with respect to the baking qualities, and specifically that this Vimin Flour must give baking satisfaction, is it your idea that it have baking qualities substantially equivalent to the baking quali-
1398 ties of flour as we now know it, or whole wheat?

A. More nearly flour as we now know it.

Q. And to obtain that, it would be necessary to set some minimum degree of purification?

A. It might be.

Mr. Goodrich: I think that is all.

Presiding Officer Willcox: Any other questions of Mr. Hardenbergh?

Cross-Examination by Mr. Armstrong.

Q. I would like to ask this question in connection with the proposed labeling of Vimin Flour. Would you say the consumer would be better informed as to quality if the name "Pillsbury's Best Vimin Flour" is used rather than the name "Pillsbury's Vimin Flour"?

The Witness: Will you read that question again, please?

(Thereupon, the last question was read by the Reporter.)

The Witness: If there are definite minimums for Vitamin B_1 established and Pillsbury puts out "Pillsbury's Best Vimin Flour" and it is in accordance with the specifications, I think the consumer would get a very satisfactory product.

Does that answer your question?

1399 By Mr. Armstrong:

Q. There was no intention to refer to any particular company here.

A. I understand that.

Q. The thought I am bringing out was that if the brand names are dropped in the labeling of the Vimin Flour, the consumer may not be informed, or at least, will have to form new conceptions of flour quality as regard the Vimin Flour, whereas if the old brand names are continued in use, the consumer is already informed as to the

quality, and it will be merely adding the additional vitamins to that product.

A. That is my idea, exactly. Let us put it this way: If Pillsbury puts out Pillsbury's Best Vimin Flour, which is their best grade of flour, and they also put out, if they have such a brand, just Pillsbury's flour, and it is recognized by the trade that Pillsbury puts out Pillsbury's Best Vimin Flour and Pillsbury's Vimin Flour, and they know Pillsbury's Best, they will probably buy it. And if they have been satisfied with Pillsbury's flour heretofore, they will probably buy Pillsbury's Vimin Flour.

There is a distinct and definite value in maintaining the mill brands in connection with the name "Vimin Flour."

Presiding Officer Willcox: Would that be affected by the method of preparation of Vimin Flour?

1400 If you used longer extraction flour, would that change its label from the milling point of view in some cases?

The Witness: This very long extraction flour under discussion has not been made commercially to any extent, and I do not know any mill at the present time which has an established mill brand for such a long extraction flour. If they start to make it, they will probably get a new brand. Our company would not take our best brand and put it on the long extraction flour.

Mr. Goodrich: What is there about the extraction, long extraction flour, which makes it undesirable to the consumer?

The Witness: I don't know.

Mr. Goodrich: That is all.

Presiding Officer Willcox: Any further questions?

Mr. Lee: Yes, Dr. Lee, Standard Brands.

Cross-Examination by Mr. Lee.

Q. That name, I understand, is spelled V-i-a-m-i-n?

A. No, V-i-m-i-n.

Q. And the "Vi" is the Vitamin B?

A. The "Vi" is vitamins and the "min" is minerals.

Q. What minerals have been added?

1401 A. We have asked as additional ingredients iron and calcium.

Q. But the standard won't include those?

A. The standard of identity will not require them. Iron and calcium will be listed as optional.

Q. What will be the ash content of that flour?

A. We do not know, because if certain levels are set, minimum levels, and they are set so low that perhaps these levels might be met by very long extraction flour, we don't know what the ash of that flour would be for the simple reason that we don't know what the levels are.

Q. Don't you think the word "min", indicating minerals, would lead the public to believe they were getting a high mineral content of some special minerals?

A. Oh, no; that is merely a suggestion. Have you a better name? We are open to suggestions for names, sir.

Professor Harris: I am Professor Harris, from M. I. T., of Cambridge. I would like to ask a few questions.

Cross-Examination by Professor Harris.

Q. I would like to know how much it would cost per barrel, to bring the riboflavin content of flour up to 85 percent extraction?

1462 A. I would rather have you ask that question of some of our later witnesses who are more qualified in these figures than I am.

Q. I hope before they go on the stand, they will prepare that information, not only with respect to riboflavin but with respect to other vitamins you mentioned.

You say it is not economically possible to do that? I would like to see the proof that that is so.

A. I didn't say that.

Q. I understand you to say it was an expensive requirement.

A. Wait a minute.

Off the record.

Presiding Officer Willcox: I think this had better be on the record.

The Witness: In its pure form—I made the statement that I was told that today riboflavin in its pure form was very expensive and if all the mills wanted to put it into their flour, there was not sufficient supply to let them do it.

By Professor Harris:

Q. Riboflavin could be put into some flour, and you stated it was a bit expensive for it to be done that way, perhaps?

A. That is true. Mr. Goodrich asked why in the 1403.4 5 parenthesis it was stated riboflavin in some form, and I said because riboflavin was not available today in large quantities at a desirable price.

Mr. Strowd: Isn't it true that it will depend on what figures are filled in for the minimum?

The Witness: That is correct.

By Professor Harris:

Q. My question has to do with bringing flour to the 85 per cent extraction level.

A. Along that line, when you talk about riboflavin at 85 per cent extraction, I hope you will question our technical men as to the methods of running tests, and so forth and so on.

Presiding Officer Willcox: Any further questions of this witness?

Mr. Gillette: Yes, sir.

Cross-Examination by Mr. Gillette.

Q. In speaking of benzoyl peroxide, you provided for the use of gypsum and magnesium carbonate. Was there any intention of excluding—

A. When we wrote this No. 5, we simply wrote it as we understood that it really was in 15.000. We are not trying to change the information in regard to benzoyl peroxide and the bleaching agents at all over what was all the 1406 information that went into 15.000, and if there is anything in there which technically makes it appear or actually does affect these bleaching agents, we are perfectly willing to change it so that the bleaching proposition in this suggested 15.010 would be the same as 15.000.

Presiding Officer Willcox: Any further questions?

(no response.)

You may be excused, Mr. Hargenbergh.

(Discussion off the record.)

The Witness: In this 15.010, the suggested 15.010, through error in copying this thing we neglected to include as optional ingredient, bromate. We had quite a little bromate argument in connection with 15.000 and we originally wrote up this 15.010 with bromate in and why it was left out when we rewrote it again, I don't know; but we want it in there.

Mr. Goodrich: That is potassium bromate?

The Witness: Yes; I am sorry it was omitted on this written statement and we would like to have the privilege of correcting the written statement which was given to the stenographer for the record.

Mr. Goodrich: I think the record will show that.

The Witness: Just the same as 15.000, and bromate 1407 would be the same as 15.000.

Cross-Examination by Mr. Goodrich.

Q. Do you have any evidence at all with respect to the action of potassium bromate in the presence of thiamin, riboflavin, nicotinic acid, or any of the minerals you have suggested as optional ingredients?

A. I have not.

Q. Do you have any evidence with respect to the requirements in the Dietary, or deficiencies in the Dietary of the class of persons using bread or flour with potassium bromate added so as to demonstrate a need for these nutrative additions?

A. We are not asking for this potassium bromate as an optional ingredient from the point of view of nutritional value.

Q. I understood from the original hearings that flour and bread with potassium bromate added went to a very limited class of users, a number of small bakers in the Eastern part of the United States, and so forth.

My question is whether or not, in that class of persons, there are the Dietary deficiencies which your additions would cure or supplement.

A. I don't know, sir. I would rather have you ask that question of some of the experts who will follow, who 1408 are more familiar with the Dietary or nutritional needs in various sections of the country.

Q. Is there any material available as to whether or not potassium bromate will have the reaction or the properties claimed for it at the original hearing when in a mixture containing these nutritients in the form of vitamins and minerals?

The Witness: Will you please read that question?

(Thereupon, the last question was read by the reporter.)

The Witness: I think Dr. Sherwood will be able to answer that when he is on the stand. I am not a technical baker and I can't answer it.

By Mr. Goodrich:

Q. Are your reasons for recommending bromate in Vimin Flour the same as the reasons stated in the testimony with relation to Section 15.000?

A. Yes.

Mr. Goodrich: That is all.

Presiding Officer Willcox: Any other questions of this witness?

(No response.)

That will be all, Mr. Hardenbergh.

Mr. Goodrich: One more question, please.

1409 By Mr. Goodrich:

Q. The testimony originally was that the potassium bromate was added to a high protein flour, one containing in excess of 12 per cent protein, I believe. This Vimin Flour would not be restricted to flour with such protein content, would it?

A. Oh, no.

Q. And there would have to be some provision made to eliminate the potassium bromate from the low protein flours made into Vimin flour?

A. I don't think so—

Q. How would that be regulated?

A. —any more than it is in 15.000. The statement was made that potassium bromate was added to relatively high protein flours because, first, that is the flour in which it does the most good; and second, that particular kind of flour is that which is required by these relatively small bakers, very largely through the East, and the introduction of the potassium bromate in the flour gives better results than if they tried to put it in in the bake shop. There is no reason why the potassium bromate if included in this 15.010 should be in any different situation or restriction than it is in 15.000.

Q. It should be added under the same conditions to both flours?

1410 A. It should be added in both types of flour; what we are trying to do is to cooperate and we feel that we can cooperate best by having this thing so we can get this vitamin B_1 into all the flours we are making, and putting on the market today, and offering it for sale, and having success with it.

If you would like the information, Mr. Thomas just called my attention to the fact that potassium bromate is especially helpful in the development of the texture, and

so forth, especially in connection with long extraction flours.

Q. Is it your idea this potassium bromate is added there be a label declaration of that fact?

A. Yes.

Q. If it is added to your Vimin flour, how will the consumer know if it is not added for its nutritive properties as these other minerals and vitamins are added?

A. He wouldn't, any more than the word "bleached." How is he to know it is not added now for—

Q. That is what I am asking you. Should there be some warning to the consumer that it is not a nutritive ingredient?

A. I don't think so. I think the more you try to complicate the labels and the more you put on the bag, the greater difficulty you are going to have and the more
1411 confusing the whole proposition will be to the consuming public.

If the industry, the nutritionists, the Government, talk Vimin Flour and you can get the people in the lower income groups—perhaps all over over—we will forget the lower income groups; if you can get the people, the housewives who work in the coal fields and the big industrial centers, who are not going to read the whole front and back page on the bag to find what they are going to get, if you talk Vimin Flour, Vimin flour, Vimin flour, get them to buy Vimin flour, I don't think it makes any difference whether it is bromated and whether it is not for the sake of nutrition, but "This flour is bleached but you must not confuse that fact with the nutritional elements in it"—you have to pound Vimin Flour if you are going to put this thing over.

You will have to label the optional ingredients, but so far as the public reading—

Q. In view of your testimony that only Vitamin B_1, is a required ingredient and nicotinic acid, riboflavin, calcium and iron, the optional ingredients, the main reliance of the consumer will depend on reading the declaration of optional ingredients.

Vimin Flour as applied to this product in which Vitamin
B_1 is the only required ingredient, is not informative
1412 to the consumer. The justification for using "Vimin" is that the product will grow in consumer acceptance and at one time or other minerals may be the required ingredient, or, is it your idea that there should be some assurance to the consumer that they will know that they

are getting a nutritive element rather than a bromate for the loaf properties and the dryness of the dough?

A. It is our idea that if everyone is interested in this proposition and wants to make a success of it, we can't jump into this thing 100 per cent from the point of view of the nutritional elements, as we would like to.

We must learn to stand before we can walk or run.

Please don't get the idea that we are trying to block this proposition. We are for it, but we don't want to go faster than the industry can pick the thing up and go with it. And we are recommending at this time B_1 with the idea that if we could be successful and get this Vimin Flour going good, in a short time we will have these other elements, the amount that should be specified as minimum, and if they are available and they do not unduly affect the price and are administered, we will have to be down here again on a proposition that this Vimin Flour must contain some of these other things in specific amounts.

Q. Then, for the present at least, the declaration 1413 of optional ingredients is the consumers' only protection in knowing what they are getting in this Vimin Flour?

A. That is right, other than that the flour would have to have B_1 in it.

Q. They would know they were getting that, but in order to determine exactly what they were getting, they would be required to observe the declaration of optional ingredients?

A. That is right.

Q. And if potassium bromate be included in a list of calcium carbonate, or mono-calcium phosphate, or something like that and under that potassium bromate, the average consumer would assume that potassium bromate was a nutrient in the same form as mono-calcium phosphate?

A. I think that would be simple to control in the labeling. If you put bleached and bromated on the label and under that listed your optional nutrients, I don't see how there would be any confusion.

Q. That is what I was getting at. Mr. Hardenbergh, if, for example, the Vitamin B_1 in your Vimin Flour came entirely from a selection of mill streams high in Vitamin B_1 on the one hand, and all came from the addition of synthetic thiamin on the other hand, would there, in your opinion, be such a difference in baking qualities as to render the products distinguishable, one from the other?

1414 A. Very much so.

Wait a minute. You are talking about a short patent, a short extraction flour?

Q. With thiamin chloride added in synthetic form, and the other a long extraction flour from a selection of mill streams high in B_1, of different baking qualities.

A. They would differ more in appearance than in baking qualities, and that depends on how long an extraction is necessary in order to reach the limit somebody might have in mind. If you get that very high, it will materially affect the baking qualities.

Q. An 80 percent extraction flour—Will that differ materially from the short patent flour built up with synthetic thiamin chloride to an equivalent B_1 content?

A. Dr. Bailey will be here tomorrow with some information and actual samples of bread. We can show you those things.

Q. Fine. I think that is all. Thank you.

Presiding Officer Willcox: Any further cross examination of Mr. Hardenbergh?

Mr. Bean: Yes; I have a question.

By Mr. Bean:

Q. Mr. Hardenbergh, I judge from what you said that you think it would be unwise to restrict the use of potassium promate in the use of this Vimin Flour, or other
1415 flours, to a flour above a certain minimum protein content.

Q. It is our idea to have the same information as was put in in connection with 15.000 apply to this 15.010. Isn't that the best way to clear that up?

Q. But there should be no restriction on 15.000?

A. There is none.

Mr. Campbell: Mr. Presiding Officer, I think it is obvious, but in this proposed definition, it has been designated as 15.010, and, of course, that number has been preempted by durum wheat—

Presiding Officer Willcox: I assume the numbers will be rearranged.

Any further questions of Mr. Hardenbergh?

(No response.)

You may stand aside, Mr. Hardenbergh.

(Witness excused.)

Presiding Officer Willcox: I might say that those persons who are here and participating in the proceedings and who have not filed notices of appearance, should do so.

Mr. Goodrich: I will bring the forms up immediately after lunch from the Hearing Clerk's room.

Presiding Officer Willcox: We would like to have the names of the persons appearing and their repre-
1416 sentative capacities, if any, for the record.

We will take a five minute recess.

(Brief recess taken.)

1417 Presiding Officer Willcox: There are some appearance forms here now, and if those of you who have not filed them at the earlier hearing will fill them in and hand them to the reporter, please.

Is Dr. Harris here? Do you want to give your testimony now?

Whereupon ROBERT S. HARRIS was called as a witness on behalf of the Cream of Wheat Corporation, and having been first duly sworn, was examined and testified as follows:

Presiding Officer Willcox: Please state your full name and occupation for the record.

The Witness: Robert S. Harris.

Mr. Bull: Mr. Bull of the Cream of Wheat Company. I would like to ask him some questions.

Mr. Goodrich: You are presenting this witness for the Cream of Wheat Company?

Mr. Bull: Yes.

Direct Examination by Mr. Bull.

Q. What is your education and training in connection with nutritional work, Dr. Harris?

A. I have received the degree of Bachelor of Science and also of Doctor of Philosophy of the Massachusetts
1418 Institute of Technology.

Q. Of what professional or scientific societies are you a member?

A. I am a member of a number of societies, among them the American Chemical Society, American Public Health Association, Academy of Physical Medicine, the American Association for the Advancement of Science, and in connection with the Massachusetts Public Health Association I am Chairman of the Committee on Foods and Nutrition.

Q. What have been your professional occupations since completing your educational training?

A. I have first acted as research assistant in nutrition and Bio chemistry at the Massachusetts Institute of Technology, then as research associate and for the last four years as Assistant Professor of Bio-Chemistry and Nutrition.

Q. What is your present position?

A. I am Assistant Professor in Bio-Chemistry of Nutrition, in charge of courses on the chemistry of foods, nutrition, applied nutrition, and advanced nutrition, and also director of a research group of seven men in the field of nutrition and bio-chemistry.

Q. Have you conducted researches and investigations in the field of bio-chemistry and nutrition?

A. During the last nine years we have conducted
1419 researches on the activation of sterols to produce vitamins; anti-rachitic properties of human milk and cow's milk, and the anti-rachitic or other properties of cereals, the preservation of vitamins in storage, either in fresh vegetables, or the preservation of vitamins, especially thiamin, in canning, and nutritional values of milk proteins, and then researches on the preparation of diets for such groups as the Antarctic expedition and other similar groups which require foods which completely fulfill nutritional requirements and yet take small volumes.

Q. In what scientific journals have these investigations been published?

A. We have published perhaps thirty articles in journals such as the American Chemical Society, Journal of Nutrition, American Journal of Orthodontia, Journal of Digestive Diseases, Journal of Laboratory and Clinical Medicine, and New England Journal of Medicine, Food Research Science, the Journal of Industrial Engineering Chemistry, and similar journals.

Q. In addition to this work, have you participated in investigations for the Cream of Wheat Corporation?

A. Yes, I have.

Q. What was the nature of your work for the Cream of Wheat Corporation?

A. The main part of my work was to set up and
1420 supervise experiments either of a bio-chemical, a nutritional or clinical nature, in other institutions and laboratories.

Q. Who were the investigators in this work, and what were their qualifications?

A. There were six investigators in this work: Professor John R. Millan of the University of Rochester; Professor of Physiology in Rochester Medical School, and at one time Editor of the Journal of Nutrition, and at one time also President of the Institute of Nutrition.

The second investigator was Dr. Morris Blatt, Pediatrician of Chicago, Professor of Diseases of Children in the University of Illinois Medical School, in charge of the Pediatric Department of the Cook County Hospital and also in charge of the St. Vincent's Orphanage of Chicago.

Also Dr. Louis K. Diamond, Instructor of Pediatrics at the Harvard Medical School, one of the best authorities on blood formation and hemoglobin formation, in charge of a section of the Infants and Children's Hospital in this field;

Dr. R. Cannon Neely, a pediatrician, also of Harvard Medical School, who is in charge of the Brookline Health Center, in Brookline, Massachusetts, and also an instructor in the Department of Pediatories;

1421 Also Professor H. B. Pierce, Professor of Bio-Chemistry in the College of Medicine of the University of Vermont; and

Professor R. G. Daggs, Professor of Physiology in the College of Medicine of the University of Vermont.

Q. What were your recommendations as to the types of nutritional ingredients which should be added to regular Cream of Wheat to improve its nutritional value?

A. After surveying the composition of regular Cream of Wheat, and the composition of whole wheat, and the part which a product such as Cream of Wheat plays in the nutrition of children and infants as well as adults, it was recommended that Cream of Wheat be enriched with thiamin, with calcium, with phosphorus, and with iron.

Mr. Goodrich: Let me get those; thiamin, calcium, phosphorus and iron?

The Witness: Yes.

By Mr. Bull:

Q. Why were these ingredients recommended?

A. For two reasons, mainly, one, that these ingredients among others were removed from wheat during the manufacture or processing to prepare farina, and second, that especially thiamin, calcium and iron tend to be deficient in the dietary of especially the younger child.

Q. Does this new Cream of Wheat that is now
1422 manufactured contain these ingredients?

A. Yes, it does.

Q. Is not disodium phosphate added now to new Cream of Wheat?

A. Yes, it is.

Q. What was the purpose of this addition?

A. As a result of experiments conducted mainly by the consulting firm of Arthur D. Little, Inc., of Cambridge, consulting chemists and engineers, it was demonstrated that by the addition of small amounts of disodium phosphate the cooking time of Cream of Wheat could be greatly shortened, and it was therefore added for this purpose.

Q. Have any tests been made to ascertain whether the addition of disodium phosphate to Cream of Wheat shortens the cooking time?

A. Yes, there have been three types of tests conducted, the first of a bio-chemical nature, invitro experiments, in which the break-down of the starches of farina was measured. The second experiments were of an animal nature, using stomach tubes to recover cereal so digested, and a third type of experiment conducted by Dr. Merlin of Rochester in which experiments of a semi-clinical nature on medical students, in which the same measurements were made, and in all cases, in these three kinds of ex-
1423 periments, with various techniques, the evidence was clear that the digestion was enhanced when Cream of Wheat was cooked with a disodium phosphate added.

Q. Were any clinical tests made to determine whether this addition of disodium phosphate was deleterious to man?

A. Yes, a clinical test was conducted in the Brookline Health Center by Dr. Neely and his group, on 48 normal infants, in an out-patient study, lasting 120 days. Half of these infants were fed regular Cream of Wheat, and the other half Cream of Wheat which had had added to it disodium phosphate, plus some wheat germ. These cereals were cooked in a central kitchen, in prescribed amounts, that is, amounts prescribed by the pediatrician in charge of the study. These prescribed amounts were delivered by special truck to the households of each of the children in the study, and at least every week a nurse visited the home and the children were examined every month in the clinic by the nurse and the doctor.

Observations were made on weight increase, the sitting

and standing height, the circumference of the head and chest, mental and physical development, appetite, the number and character of the stools, and the incidence of infection; and this study failed to show any difference in the two cereals, that is, ordinary farina, as compared with the Cream of Wheat fortified with disodium phosphate.

1424 Q. Is it your opinion that disodium phosphate is a harmless substance, that assists in the cooking of farina and should therefore be allowed as an optional ingredient of farina?

A. As a result of experiments which were conducted first on animals, and then on human infants, it is my opinion that disodium phosphate is a harmless substance, assists in the cooking of farina, and should be allowed as an optional ingredient of farina.

Q. How much calcium is there in whole wheat?

A. The amount of calcium in whole wheat, of course, varies considerably, perhaps five one-hundredths of one per cent is a fair value.

Q. How much calcium is there in farina?

A. There is perhaps two one-hundredths of one per cent of calcium in farina.

Q. Then farina contains less calcium than whole wheat?

A. Yes, it contains less than half as much.

Q. What are the functions of calcium?

A. Calcium has many functions. The chief functions are with respect to the formation of bones and teeth, in connection with the clotting of the blood, and in the activation of muscles, the muscle action.

Q. Does calcium tend to be deficient in the dietary?

1425 A. It tends to be deficient in the dietary of certain groups in the country, especially in those groups that do not consume large amounts of milk, which is our best source of food calcium.

Q. In what form is calcium added in new Cream of Wheat?

A. As tri-calcium phosphate.

Q. Why was calcium added?

A. It was added partly to make up for the deficiency—to make up for what was taken from the wheat in the preparation of farina, and partly was added in the form of a phosphate in order that it would not interfere with the quick cooking effect of the disodium phosphate.

Q. Have any clinical tests been conducted to measure

the availability of calcium added in the form of tri-calcium phosphate?

A. Yes, a clinical test to measure the retention value of calcium when added to Cream of Wheat in the form of tri-calcium phosphate has been conducted.

Q. Have the results of this work been published?

A. This work was conducted by Drs. Pierce and Daggs, and this work has been published in the Journal of Nutrition, volume 19, pages 401 to 414, 1940.

Q. Will you please read the final paragraph in the summary and conclusions of this published article?

1426 Mr. Goodrich: Just a minute. Do you have five of these to offer for the record? If so we would like to have them.

Mr. Bull: Yes.

Mr. Goodrich: Go right ahead.

The Witness: I would like to read two paragraphs in the summary and conclusion of this article:

"With the same basal diet the retention of calcium and phosphorus was determined when 200 mg. of milk calcium was replaced by 200 mg. of calcium in the fortified cereal. In one period the storage of calcium and phosphorus was significantly better when these two elements were supplied in part by the fortified cereal rather than by milk, while in a second period of comparison the availability of calcium and phosphorus as measured by retention was the same."

And then the final paragraph in this section:

"For maximal retention of calcium it was necessary to have a daily intake of over 700 mg. of calcium. When a part of the milk calcium of an adequate diet was replaced by an equivalent amount supplied by tri-calcium phosphate in a fortified cereal, utilization as measured by retention was equally good from milk and cereal."

1427 Q. Why was the comparison made against milk calcium?

A. The comparison was made against milk calcium, firstly because milk calcium is perhaps our chief source of food calcium, and secondly, because experiments of this type, or in experiments of this type, milk calcium is used as the standard of reference.

Q. In your opinion is tri-calcium phosphate a harmless and effective source of calcium?

A. In view of the experiments which have been conducted, especially this clinical experiment on ten inpatient

children, it is my opinion that tri-calcium phosphate is a harmless and effective source of calcium.

Mr. Goodrich: That is on page 402 of this paper which you have read, by Pierce and others, this experimental data to which you refer now?

The Witness: I just mentioned the ten children, that is mentioned there.

Mr. Goodrich: That is the clinical experimentation to which you refer and on which you base your opinion?

The Witness: That in addition to experiments which have been conducted on animals. In all cases clinical experiments follow the animal experiments.

Mr. Goodrich: All right, sir.

1428 By Mr. Bull:

Q. Then, is it your opinion that tri-calcium phosphate should be allowed as an optional ingredient in farina?

A. In view of the fact that I consider that farina should be enriched with calcium and in view of the fact that tri-calcium phosphate in farina in this form is at least as good a source of calcium as milk calcium, it is my opinion that tri-calcium phosphate should be allowed as an optional ingredient of farina.

Q. What is the iron content of whole wheat?

A. Again, the iron content of whole wheat varies considerably from one sample to another; perhaps 15 milligrams per hundred grams might be taken as a fair value.

Q. What is the iron content of ordinary farina?

A. The iron content of a large number of samples which have been studied averages about 2 milligrams per 100 grams.

Q. Has this nutritional importance?

A. Iron has considerable nutritional importance, especially in the formation of hemoglobin, which is essential for physiological health.

Q. Then you think that farina should be enriched with iron?

A. In view of the fact that farina is given to

1429 children very early in life, in view of the fact, also, that milk is admittedly deficient in iron, and in view of the fact that infants develop a degree of anemia which is benefited by the feeding of iron, of available iron, it is my opinion that farina should be enriched with some type of iron.

Q. In what form is iron added to new Cream of Wheat?

A. It is added in the form of iron phosphate.

Q. Why is iron phosphate used for this purpose?

A. Because it has been proven to be a source, or an effective source of iron, and because the phosphate group makes it compatible with the disodium phosphate which is used in the quick cooking product.

Q. Has a clinical study been made to determine the availability of iron in the new Cream of Wheat?

A. Yes, a clinical study has been made on this subject, by Dr. Diamond of the Infants' and Children's Hospital in the Harvard Medical School, in Boston.

Q. Will you describe that experiment and the results which were obtained?

A. In this experiment, 26 in-patient infants were used. The procedure was to feed these very young infants for a period of ten days, on a diet which contained milk and mixed farina, that is, several brands of ordinary market farina were mixed in equal quantities.

1430 During the second period of about twelve days, or fifteen days, these infants were fed a fortified farina—that is, the new Cream of Wheat, to which there had been added iron phosphate.

During a third period of fifteen days, these same infants were fed a medicinal source of iron in the form of ferrous salt, and the amounts given were graded according to the experiment. The effect of the iron and the available amount of the iron in the new Cream of Wheat was measured by determinations of the amount of hemoglobin, the number of red cells and by the meticulous response of these infants to the iron.

It has been definitely shown that if one adds to the dietary more iron the reticulocytes increase, the number of reticulocytes in the blood increases and the extent of this increase, and the length or duration of this increase is proportional to the iron which is fed.

These reticulocytes are new red blood cells. If after feeding a source of iron one feeds a second kind of iron, and in the same amounts, and there is a second reticulocyte response, this is evidence that the second type of iron is more available than the first type of iron. If, however, on feeding the same amount of iron to the infants during that second period, there is no second reticulocyte response, this is evidence that the second kind of iron is

at least either less available or no more available
1431 than the first iron which was fed, and by grading the amounts of iron fed, as medicinal iron, during the second period, it is possible to arrive at a determination which is accurate within perhaps 5 per cent or maybe as much as 10 per cent, a determination of the availability of iron in the food.

Using this procedure on the new Cream of Wheat, and on 26 infants, Dr. Diamond reports as follows:

"Fortified Cream of Wheat fed to infants between three and five months of age, as their first soft-solid food, acted as a source of iron, as judged by reticulocyte response, by the seventh to tenth day after this feeding was begun, as well as by the increase of retjculocyte and hemoglobin levels. The iron of the fortified Cream of Wheat was found to be more than 80 per cent as available as medicinal iron, and essentially equivalent to medical iron in effectiveness."

I might add that this technique has been used by Dr. Diamond on a series of foods. The articles are in process of being published, and furthermore, in work which we have done, our laboratory has done, in conjunction with Dr. Diamond's laboratory, his results on infants indicated that the rat is a reliable animal for the estimation
1432 of the availability of iron in food substances.

Q. Have the results of this particular experiment been published?

A. No, the results of this experiment have not been published. The manuscript is nearly completed, and it will be published within a few months, either in the Journal of Pediatries or in the American Journal for the Diseases of Children.

Q. Why was the comparison made against ferrous sulphate?

A. Well, ferrous sulphate, or the trade name of the product used in this case was Field Salt, was used as a medicinal source of iron, it being perhaps as well available as any other iron source.

Q. In your opinion, is iron phosphate in any way harmful, and is it an effective source of iron?

A. During the course of this clinical investigation, there was no evidence of any harmful effect of ferric phosphate, and there was definite evidence of beneficial effects having been produced.

Q. Is it your opinion that iron phosphate should be allowed as an optional ingredient of farina?

A. Farina is admittedly deficient in iron, and since iron phosphate has been shown clinically to be an effective source of iron, it is my opinion that it should be
1433 allowed as an optional ingredient of farina.

Q. How much Vitamin B_1 or thiamin is there in whole wheat?

A. Again the amounts of thiamin in whole wheat vary with the sample. Perhaps 165 international units per hundred grams might be taken as a fair amount.

Q. How much Vitamin B_1 is there in farina?

A. Repeated assays have shown that farina contains about 14 international units per 100 grams.

Q. Then farina contains much less thiamin than whole wheat?

A. Yes, farina contains perhaps a twelfth as much thiamin as whole wheat.

Q. In your opinion, is it important that farina should be enriched with thiamin?

A. I think that there is no doubt whatever that it should.

Q. Do others confirm your opinion in that regard?

A. Yes, there are a number of others who confirm this opinion, and I will quote only one such person. Dr. Cowgill, in an article published in the Journal of the American Medical Association, Volume 113, pages 2146 to 2151, 1939, makes the following statement:

"There are grounds for believing that American dietaries as a whole are unsatisfactory with respect to
1434 the content of Vitamin B_1. The examination of available food statistics as well as of recently collected American dietaries, the observations of clinicians concerning the high therapeutic value of Vitamin B_1, in conditions hitherto not suspected to be due to lack of this factor, and the observations of the value of added Vitamin B_1 to the dietaries of many children, all support this belief.

"It is believed that prosecution of a program fostering addition of Vitamin B_1 to staple American foods according to the principles discussed in the present report, would be definitely in the interests of the public."

Dr. Cowgill is a member of the Council on foods of the American Medical Association, and this article was published under the auspices of that Council, and there are many other authors whom I might quote, but I think that

there is a general agreement that an effort in this direction is a very sound one.

Q. In the milling process, are other vitamins than B_1 removed?

A. Yes, in the milling of wheat you might say all of the vitamins present in wheat are removed to greater or less degrees. Among these are riboflavin, nicotinic acid, and pantothentic acid, Vitamin B_6, Vitamin E.

1435 Q. Does wheat germ contain these vitamins which are removed?

Mr. Goodrich: One moment, please. What are all of those? B_1, riboflavin, nicotinic acid, and pantothentic acid and Vitamin E?

The Witness: Yes.

By Mr. Bull:

Q. Does wheat germ contain these vitamins which are removed?

A. Wheat germ contains, I believe, all of these vitamins in varying amounts.

Q. Is that why wheat germ is added to the new Cream of Wheat?

A. Wheat germ was added to the new cream of wheat, in an effort to preserve insofar as possible the wheat nature of Cream of Wheat, and also to add these other factors in addition to thiamin to whatever extent was possible.

Q. Has any clinical work been done to show the significance of addition of this wheat germ to the new Cream of Wheat?

A. No clinical experiment was conducted on this subject alone. However, a clinical study has been conducted by Dr. Blatt, in Chicago. This experiment was made on 229 children between the ages of several months, and
1436 four years. This experiment continued over a period of a year, and during this study a comparison was made between the new Cream of Wheat as it is now sold, and a mixed sample of commercial farinas. The dietaries of these children were identical, that is, with respect to their ages, with the exception of the cereal portion.

The conclusions of Dr. Blatt's work are as follows:

"Farina enriched with iron, calcium, and wheat germ was well tolerated by normal infants on the usual milk diet, did not increase the number of stolls, nor did it cause constipation. This enriched farina caused an increase in the body weight, and the red blood cell count of these infants, which was superior to increases in similar infants

fed ordinary farina. This superiority has been established as statistically significant. The height of the children fed the enriched, farina showed a trend of superiority over that of those fed control farinas, but the significance of this trend was not established."

Q. Is it your opinion that wheat germ should be allowed as an optional ingredient in farina?

A. Before answering that question, I might add that Dr. Diamond's report of this investigation has been,
1437 the manuscript of this investigation has been completed, and I believe either has already been, or will very shortly be submitted for publication in a proper pediatric journal.

It is my opinion that farina should be enriched with thiamin, or with wheat germ.

Q. About how much wheat germ would you have to add in order to raise the thiamin content to that of whole wheat?

A. One would have to add perhaps 16 per cent of wheat germ to farina in order to raise the thiamin content to the value of whole wheat.

Q. Would this greatly alter the physical appearance and flavor of farina?

A. Yes, it very definitely would.

Q. Is there another way in which this restoration of thiamin can be accomplished?

A. Yes, it is possible to accomplish the same thing by adding thiamin in another form, for instance, as thiamin-chloride.

Q. Is there any reason why thiamin-chloride should not be allowed as an optional ingredient of farina?

A. I can think of no reason whatsoever.

Q. In the same manner, is there another way in which riboflavin can be restored to farina other than by
1438 addition of wheat germ?

A. It is possible to add riboflavin either in a concentrate form or in the form of crystalline riboflavin.

Q. Do you know of any reason why riboflavin should not be allowed as an optional ingredient of farina?

A. No, I do not.

Q. Are you familiar with the stone mill process of making flour?

A. Yes, I have read very much about this process.

Q. Was not essentially all farina produced by this process at one time?

A. According to the way farina was manufactured, before the institution of the roller mill process, essentially all farina was produced by the stone mill process in the past.

Q. How was that farina different from the farina we know today?

A. Well, the farina of those days contained perhaps twelve times as much Vitamin B_1 or thiamin, at least two times as much riboflavin, about two times as much calcium, and about three times as much iron, and contained considerably more bran.

Q. Then there has been a great change in farina in the last fifty years?

A. Yes, due to the refinement of farina during
1439 the past sixty years, there has been considerable change in the constitution of farina.

Q. Then, in reality, the allowance of these nutritional substances as optional ingredients of farina would tend to enrich farina making it conform more closely to the old-fashioned nutritionally superior farina.

A. Yes, the allowance of the ingredients which I have suggested would make farina approach the old-fashioned farina much more closely in nutritional values.

Q. Well, in behalf of the Cream of Wheat Corporation, what ingredients do you request as optional for farina?

A. I request that the following ingredients be allowed as optional ingredients of farina:

Disodium phosphate, tri-calcium phosphate, iron phosphate, wheat germ, thiamin, and riboflavin.

Mr. Bull: That is all.

Presiding Officer Willcox: I think before the cross-examination of Dr. Harris, we might adjourn for lunch and I think we might adjourn until two o'clock. After the examination of Dr. Harris is completed, we will adjourn until tomorrow morning.

(Whereupon, at 12:30 o'clock p. m., a recess was taken until 2:00 o'clock p. m. of the same day.)

1440 Afternoon Session.

(The hearing was reconvened at 2:00 o'clock p. m.)

Presiding Officer Willcox: We will proceed, gentlemen.

Whereupon

ROBERT S. HARRIS, resumed as a witness for the Cream of Wheat Corporation, and having been previously sworn, was further examined and testified as follows:

Mr. Bull: Mr. Presiding Officer, I would like to offer in evidence the five copies of this article by Dr. H. B. Pierce and Dr. R. G. Daggs, on "The Retention of Calcium and Phosphorus by Pre-School Children," which appeared in the Journal of Nutrition, Volume 19, No. 4, April of 1940.

Presiding Officer Willcox: Is there any objection to the receipt of this in evidence, or does anyone wish to look at the document before it is received? (No response.)

If not, it will be received in evidence, and marked as an exhibit "O," on behalf of the Cream of Wheat Corporation.

(Document "The Retention of Calcium and Phosphorus by Pre-School Children" received in evidence and marked INDUSTRY EXHIBIT "O.")

1441 Presiding Officer Willcox: Dr. Harris wants to make one correction in his statement this morning.

The Witness: This morning I stated that the iron content of whole wheat was in the order of 15 milligrams per 100 grams and there was a mistake in that. That is the value I have per pound, and if it is calculated in terms of per hundred grams, the iron content is approximately three milligrams per 100 germs, and I think that that is the correct figure.

Presiding Officer Willcox: Is your figure on the content of farina correct?

The Witness: That is correct.

Cross-Examination by Mr. Goodrich.

You are connected with the Cream of Wheat Company in an advisory capacity?

A. I have been at times in the past, at the time this work was done.

Q. And you directed the investigation of these men of whom you spoke in your original testimony?

A. Yes, I located the investigators, planned out with them the type of experiment which was to be done, followed it more or less closely while it was being conducted, and passed on the work when it was finished.

Q. Farina is primarily a baby food, is it not?

1442 A. I would not say that farina is a baby food; I would say that farina can be eaten by persons of all ages, and because of its milled character it can be used by babies and perhaps by invalids, but I would not say that that makes it a baby food. It just can be adapted to infant feeding.

Q. And it is not used primarily for infant feeding, in your opinion?

A. No, I would not say that it is, no. In fact it is my understanding that a large part of the farina business is toward the feeding of individuals between two and 12 years old.

Q. A large part of it?

A. Yes, that is right, and infants cease to be infants, as I understand it, when they are a year old.

Q. You recommend the addition to farina of disodium phosphate, ferric phosphate, wheat germ, thiamin chloride, and riboflavin concentrate?

A. That is right.

Q. Are each of these products being added to Cream of Wheat today, or do you know?

A. They are being added today.

Q. To what you call the new Cream of Wheat?

A. That is right.

Q. In what amounts, please, sir, if you can tell us?

1443 A. I believe the company would prefer that I give you a range of values rather than the exact amounts.

Q. All right.

A. The stabilized wheat germ between 4 and 8 per cent; ferric phosphate, between one-tenth and two-tenths per cent; tri-calcium phosphate between 1 and 2 per cent, anhydrous disodium phosphate between five-tenths and one per cent, and calcium phosphate, between one-tenth and two-tenths per cent.

Q. That is tri-calcium phosphate?

A. Yes.

Q. Now, what of riboflavin; are they adding that now?

A. No, the point I wish to make is that at the present time riboflavin is being added in the wheat germ and the request was made for thiamin and for riboflavin on the assumption that possibly in the future this company would wish to add those two substances in a form other than in wheat germ.

Q. Tell us, if you will, Doctor, how they arrived at these additions, why they made them, and how they arrived at the figures, if you know?

A. The original calculations were made on the basis of individuals of different ages, for instance, a five-year-old child, knowing the amount of milk this child
1444 consumed, and the amount of cereal it might consume, in a portion, the attempt was made originally to have the two, especially in a younger child than five years old, of the two, milk and cereal, contain as nearly as possible what we would then call the minimum daily requirements. The amounts in the final formula are not quite the same as that but they rather nearly approach that. For instance, the ratio of calcium to phosphorus in this cereal is roughly of the order of 1.2 of phosphorus, to one of calcium, which is a very nice ratio in terms of nutrition.

Q. In the fact that the Vitamin B_1 is removed from the wheat in the preparation of farina, that had nothing to do with the original fortifications, other than that that deficiency did exist, regardless of how it got there, you undertook to build it up on the basis of minimum daily requirements rather than on the basis of the content of the whole wheat berry?

A. You can't say it was on one base or the other; it was to us one basis of minimum requirements, and then see to what extent that could be satisfied in a cereal of this type. It really had nothing to do with the amount of thiamin that there is in whole wheat as compared with farina. However, I wanted to bring out the fact that there is this effect of the milling of wheat, that must be con-
sidered as being a fundamental reason why these
1445 substances might well be added to such a substance as farina.

Q. Is it your opinion that the more reasonable approach in fortification of staple American foods, as you said, is

on the basis of the minimum daily requirement of the persons to whom that food is to go, or on the basis of attaining the level naturally present in the whole wheat berry?

A. I would say that in the feeding, if one has a substance that is used in the feeding of the adult, that it is very sound to try to enrich a refined staple food substance to the extent of that food substance before it had been purified, or had been refined. However, sometimes it is important that we make an exception in the case, for instance here, it might be well to consider in addition to that the extent to which this food substance will supply the needs of the infant.

I pointed out this morning, for instance, that milk is a food that is quite deficient in iron. If a very young child is subsisting on a diet consisting of farina and milk, and little else, the child does develop nutritional anemia, and iron deficiency anemia, and it has been shown in the work that was done by Dr. Diamond, and that can be prevented and can be alleviated by, of course, supplying iron to the dietary of the individual. I think that we will all
1446 agree that it is important if it is possible to prevent such a condition from developing; and therefore, if one has a very young child, or even perhaps an infant, who is subsisting largely on milk and farina, it is best that one make an attempt through natural means, that is, through feeding means rather than through drug means, to prevent the development of that deficiency, and therefore in a case where we have a cereal substance that is used also in infant feeding as well as in the feeding of the adult, that one might make exceptions on the basis, perhaps, of iron, in following the rule that food should be enriched to the extent of their unrefined vitamin and mineral content.

Q. Why do you adopt as the base line, the level of the whole wheat or the unrefined grain?

A. I don't know what you are referring to now, but I would say that in general what investigations have been made as to what was eaten in the past, before we had refinement of food, it appears that with unrefined foods there was not the high incidence of deficiency disorders that we have today, and that a return to that condition should alleviate to a large extent this condition. Therefore it seems to be rather a sound basis to enrich foods

to either their whole unrefined basis, or to the basis, for instance of stone mill flour or something of that
1447 sort, the type of food that we consumed in those times.

Q. That is based on the hypothesis, is it not, that diet deficiency diseases did not have the prevalence in those days that they now have, and also on the assumption that an equivalent amount of cereal was eaten then as now?

A. Well, no, in answer to the first, I think, or at least the evidence indicates that diet deficiencies were not as prominent, they did exist but were not as widespread in the populatio[illegible]

On the sec[illegible] point, the consumption of wheat in those days was largely higher than it is today.

Q. The[illegible] those two things would interfere with the assumptions on which the restoration to the whole wheat level was predicated, would they not?

A. I would say yes, largely.

Q. And then in proceeding with a system of fortification of staple foods, based on those assumptions, that system is subject to serious doubt in view of the fundamental different conditions which prevailed then and now, is it not?

The Witness: Could I have that question again.

(The pending question was read by the reporter.)

The Witness: I believe that you are referring to the fact, for instance, that today we are consuming large
1448 amounts of sugar, and our dietary in "B" content has changed not only with respect to the amount of thiamin and other vitamins in whole wheat or flour that we consume but also in other foods as well. I would say that if we take the principle of fortifying to the extent of the unrefined food substance, and attempt to enrich all staple foods, not only flour, with those vitamins and minerals which they contained, that even though there has been a change in the ratios of the amount of sugar consumed, and the amount of wheat or other cereals consumed, that by following out that policy in the end the effect, would be, I think, more or less the same. In other words, by enriching flour and sugar and some of our fats, perhaps, with the vitamins, so that they would resemble more nearly the natural foods, the whole problem, I think, would be fairly well solved.

Q. Well, do you have any evidence of that, or is that just your personal opinion?

A. Well, I don't have any evidence with me. It is my conclusion as a result of my study of this whole question, that of course in the case of sugar, the difficulty with sugar appears to be that the thiamin content of sugar cane juice is not enough to take care of the metabolism of the carbohydrate in sugar, and in an instance like that, one
1449 would have to depart a little, from that principle, in order to make the sugar take care of its own metabolism, because today we rely on other foods to supply the nutritional substances which are needed for the metabolism of the carbohydrates and starches in flour and sugar.

Q. I believe that you assisted in the preparation of concentrated food for the Byrd expedition, did you not?

A. Yes.

Q. Was that based on the restoration of the natural food level, or on a scientific basis of daily requirements to the persons who would eat it?

A. It was based, of course, as far as we knew, upon the requirements of those persons that would eat it. These men were to consume 12 ounces of this material, that had a very high caloric value, and in that 12 ounces they had to be supplied with all of these food substances, in adequate amounts, and in fact they were supplied with an excess of that in order to be sure that they did not develop a deficiency, because in the past every expedition to antarctic or arctic regions has developed deficiency diseases, so that is a special case, I would say, where you have to fill in to a food that is consumed in a certain definite amount, all of those nutritional elements that are required by the individual under those peculiar circumstances.
1450 Q. You proceeded on the theory that a certain minimum daily requirement existed on each of the substances added in this concentrate, and you undertook to fulfil the daily requirements in this concentrated food?

A. Yes, and then supply an excess so that there was well in excess of this minimum requirement.

Q. You say that the restoration principle is very sound and that certain exceptions be made in the case of I believe you said, iron in the infants' diet?

A. Yes.

Q. I would like to have you spell that out a little, what you mean by "The principle is very sound." Is that based

on your idea that there was not the prevalence of deficiency diseases in the old days, and that if we got back to the old days in the restoration of this flour, the diseases would diminish in number?

A. Well, it is a confusion of a whole lot of things that has made me taken this posititon. In the first place, if you allow things to go as they now are, everybody that puts out a product decides, perhaps, to supply in that product everything that the person needs for that day, not taking account of the fact that this product is only part of a group of products that might be consumed.

We know, for instance, that in the case of thiamin, that is the important question, I think, at the moment,
1451 of most importance, that a certain amount of thiamin is required to burn sugars and carbohydrates in the food, and it seems that in general, with several exceptions, that unrefined foods contain enough thiamin to take care of the metabolism of the calories of the sugar calories, carbohydrate calories of that food, or those foods, and one has to use something as a basis, unless one uses this principle, that it would be difficult to decide upon some other principle that would be reasonable and would not bring a lot of difficulties, because then we would have to decide to what extent each of these different foods, and there are thousands of them, are present in the dietary, daily, or how consistently they are eaten, how reliable they can be as sources, and it would be difficult, also, for any group to decide how many units, for instance, they should contain, and I say one avoids a lot of this difficulty by just trying to make our foods old-fashioned again in bringing them back to their crude nutritional values.

Q. Are you familiar with the fortification of milk with Vitamin D?

A. Yes.

Q. Upon what basis was that done?

A. What is that?

Q. On what basis is that done today, on minimum
1452 daily requirements or in a restoration of the milk?

A. There are several kinds of fortified milk. One kind has—

Q. I am talking about the one with added Vitamin D and not the irradiated milk.

A. Those milks, as far as I know, contain between

400 and 430 units per quart, I believe, but I am not sure that the basis of those figures was too scientific. I think it was arrived at partly on the basis of science and perhaps partly on the basis of convenience. One would say that since the Vitamin D requirements of the infant are of the order of 400 units per quart, or 400 units per day, that it really happens that milk of that potency does a fairly good job at meeting the minimum daily requirements of the very young child.

That is, again, for instance, an exception. Milk does not normally contain anywhere near 400 units per quart but since milk and some of these cereals are the early foods of the infant, it appears advisable that milk should act as a carrier of Vitamin D, much in excess of the normal content of any milk that is produced by any cow.

Q. The same condition would prevail with respect to some of the properties in the whole wheat berry, would it not, for instance, calcium in the whole wheat berry?

A. That is right. Of course one assumes that in 1453 the very young person, milk is being consumed in fairly liberal quantities, and the amounts of calcium that might be obtained from milk would be in many cases adequate to take care of the need.

Q. I had in mind this: The calcium content of the whole wheat berry is rather insignificant insofar as the minimum daily requirements of a man are concerned?

A. Yes, I think that that is very true.

Q. And then if you built the calcium content up to the level of the whole wheat berry you haven't done anything significant in taking care of the minimum daily requirement of the person who will consume the flour?

A. That is right; bringing the calcium value of flour or farina to the whole wheat calcium value, will not do very much, maybe not even a significant amount or have a very significant value in terms of the total calcium requirements.

Q. And the same is true with respect to riboflavin, is it not?

A. I would not be willing to say that. Certainly not to the same extent, because there is riboflavin in the wheat berry, and the amounts there, although they do not measure up very high, are still of importance when one considers the fact that about 25 per cent of the calories one

consumed are in the form of wheat or wheat products
1454 so that although it is a very small amount of ribo-
flavin the amount that might be consumed in the
course of a day by a person would become more consider-
able.

Q. Has the minimum daily requirement of riboflavin been established?

A. I have sat in with many committees on this matter, and I don't think that the minimum daily requirement has been very well established, certainly not nearly as well established as some of the other vitamins, but a fairly good estimate has been given, an estimate of an amount which seems to prevent the appearance of gross riboflavin deficiency.

Q. Would building the riboflavin content of the flour up to the whole wheat level take care of one-fourth of the minimum daily requirement, assuming that 25 per cent of the caloric intake came from the flour?

A. I would have to calculate that out. I am sorry that I can't answer that. I am not sure that I can calculate it here. I don't have the data on which to do it.

Q. I guess that we can let that go.

A. I could do it and then come back with it.

Q. We will let that go for the present.

A. The point I really wish to make is that if we are going to do something to improve the dietary, when a
person has one deficiency they usually have several,
1455 due to the fact that when we refine flour, or refine
whole wheat we remove not only thiamin but several
other vitamins as well, but if you are going to make flour what it was before, make it a much better food, you should do something besides put thiamin in, if possible, and the sooner it is done, the better, and on this basis of calculation, if it is brought back to the flour level, old-fashioned flour level, rather than the whole wheat level, in all factors, not only thiamin and in these factors not because they will contribute a significant amount so much as that it will bring it back to what it was before, that a service will be done to the public in making flour a much better food than it is.

Q. Even if the material is added in insignificant amounts, do you think that that would serve any purpose?

A. I don't think that you have a right to, or I would not say that anything is insignificant, if you look at things

in terms of total nutrition, every small amount has an effect, and it may have some importance, it may not be possible to measure that effect, and if you can't measure it then you say it is not significant but physiologically because you can't measure it, does not mean that it is not significant, because it is proportionately small, small in proportion to the total daily needs, that is not a reason why you should not do a thing. The point is that
1456 there is evidence of riboflavin deficiency in our population and I think to some extent at least, flour and milling of flour has had a part in the development of that condition and I think that flour should do its part to alleviate that condition and I say its part is to at least go back to the crude flour of yesteryear.

Q. That would be the very least it should do, though, if you assume that you want to do something for the American dietary, it would seem more reasonable, would it not, to do something significant rather than taking half measures in supplementing the dietary?

A. If you are referring to calcium here, it would seem that rather than make cereal containing a large amount of calcium, cereal or flour, contain a large amount of calcium, it would be better to perhaps rely on some other food to do their part as well, and if whole wheat berry does not contain very much calcium, there is no reason to my way of thinking that flour or farina or any cereal product should contain large amounts of calcium, especially since when flour is used in baking it is a general practice, I understand, to use milk solids, and these milk solids supply considerable amounts of calcium.

Q. In building up the flour to the whole wheat level, you have not suggested anything with respect to
1457 nicotinic acid, Vitamin E, Vitamin B_6, or pantothenic acid, which you stated were present in the whole wheat berry. Can you give us the reason why you did not suggest them?

A. Well, it is a very simple explanation. You will recall the statement that in behalf of this company I requested that these be allowed as special ingredients for farina. I did not mean by that that I did not think that other things should be added in addition, and I do firmly believe that these other substances; all vitamins that are present in whole wheat, and are removed to some extent

in the refinement of whole wheat, should be allowed as special ingredients of the flour and cereal products.

Q. Is there any material available as to the place Vitamin E has in the American dietary, n the detary of man?

A. There is a confusion of articles on this question. I think the conservative conclusion to make at this time is that it has not been proven. There are some evidences that are very attractive, I would say that it is likely that Vitamin E does have a function in human nutrition, but the extent of that function and the reality of that function has not been well enough established so that one should go much further than say that we are waiting for the evidence to come in.

1458 Q. I assume the same is true with respect to Vitamin B_6 and pantothentic acid?

A. I would say that the same is true but perhaps to a lesser extent, that articles have been appearing this fall. I recall one by Dr. Spiess' group, with evidence to indicate that these vitamins do have an effect on human nutrition. I would say that the evidence is not strong enough to go out to any extent on it but there is very definite evidence that these vitamins have human functions.

Q. There is no evidence whatsoever as to the daily requirements of these vitamins, is there?

A. Well, since it would follow that since we are not too sure that these vitamins are required, that is, certainly to any great extent, then it is not possible to determine daily requirements. We first must show that the vitamin is required, and then how much is required.

Q. In spite of that; you are of the opinion that building Vitamin E and B_6 and pantothentic acid up to the level of the whole wheat berry would be a valuable addition to flour?

A. I would say it would be a safe procedure. That is the one thing that we must remember, and that is that wheat contains these vitamins and minerals, not because

1459 we need them, but because the wheat plant itself needed them, and they were harmonized in a way for the plant's metabolism, and we have to some extent developed strains of wheat, for instance, that have certain characteristics that are more or less baking characteristics which made the wheat more acceptable, so we must be a little bit careful to assume that since these things are present in wheat, that they are necessary to ourselves, but

the point is that in the past wheat has been an important item of the dietary, and in that past the dietary appears to have been very much better than it is today. It is a sound practice to try to return to those days by fortifying or enriching refined cereal products with those substances which have been removed from it and to the extent of, say a food substance of that type, seventy or eighty years ago.

Q. The quantity of the several vitamins and minerals in the whole wheat berry is dependent, as well as the appearance, upon the requirements of the plant in metabolism, is it not?

A. I would say that that is definitely so. We know, for instance, as the whole wheat berry ages, the amounts of these different factors will change. That is to a large extent the reason why different samples of wheat vary in the amount of vitamins that they contain.

In our laboratories we have done work on materials such as lettuce, and if you wrap lettuce in a
1460 paper so that it will not dehydrate, the vitamin content will continue to rise even though the lettuce has been taken from the soil, and if you make tests on the peel of apples while they are being stored, the vitamin content of that will rise, and the point is that one of the reasons why the vitamin and mineral content of a substance like wheat varies so much is, of course, due partly to varieties, and the soil in which it is grown, and the climate of the year, and also to the age of the berry, and the way it was treated in the field and the way it had been treated after it had left the field.

Q. Then restoration to whole wheat level is based upon the chance of the occurrence and the quantity of the occurrence of these products in the whole wheat berry rather than upon any scientific basis of daily requirements of humans in consuming these products?

A. That is partly true, and of course before we can set up standards as to what whole wheat contains, we must have considerable data as to what the average content of whole wheat might be.

Q. It is true, is it not, that there is as much controversy as to what whole wheat berries contain as there is as to the minimum daily requirements of the persons consuming the cereal?

A. There is more discussion of that.

1461 Q. You stated, I believe, that the most important of these nutrients was Vitamin B_1 at the present time?

A. Yes.

Q. What is the relative frequency of occurrence of acute cases of Vitamin B_1, riboflavin and nicotinic acid deficiencies, or deaths, resulting from any one or more of those deficiencies?

A. I can't answer that very accurately because I was not prepared to but I would say that the incidence of thiamin deficiency is defintely higher than the incidence of the other vitamins' deficiency that you mentioned.

Q. Are there in your opinion more cases of beriberi existing in the United States today than, say, pellagra?

A. Well, it depends on how you are going to define beriberi. If you define it in terms—

Q. I assume, any manifestation—go ahead. I was going to place it upon the basis of deaths, so that we would have something to work on.

A. I would say according to Dr. Sebrell's work, and I think he is here and might be able to talk better, there are more deaths from pellagra than there are from the other B_1 deficiencies. That would indicate, of course, that in certain parts of the country there are very extreme deficiencies.

Q. That would not indicate—

1462 A. The point I was making is that in the case of thiamin deficiency, we have a small deficiency that is more widespread, perhaps, than the deficiency due to riboflavin or nicotinic acid.

Q. Is that the basis on which you say B_1 is the most important for present purposes?

A. No, the basis was on the incidence rather than on the number of deaths.

Q. That is what I mean.

A. Yes.

Q. In your direct statement, in your statement in answer to your attorney's questioning, you stated that there are at present Vitamin B_1, calcium and iron deficiencies in the dietary of children today. I believe that is true. If I have misquoted you, be sure to correct me.

A. That does not mean that that is all there are.

Q. At least those?

A. Yes.

Q. And upon that basis you have proceeded with the restoration, shall we say, of Cream of Wheat, up to the whole wheat level?

A. Well, yes, except for the iron, and the iron is above

the whole wheat, and I have explained the reason for that.

1463 Q. Di-sodium phosphate, which is added to farina, produced by the Cream of Wheat Company, is added, you say, for its reaction in the cooking process. Who recommended that, now?

Q. The original work was done by Arthur D. Little, Inc., who are consultants for the Cream of Wheat Company.

Q. They are chemical consultants and engineers, and not nutritionists?

A. They are not nutritionists.

Q. And you have been in charge of the nutritional work, I believe?

A. That is right.

Q. Can you explain to us, please, sir, how the chemical reaction works which renders Cream of Wheat treated with di-sodium phosphate easier to cook, or renders the cooking process quicker?

A. I would rather like to be able to explain that. The effect is not entirely a change in "pH" of the cooking mixture, because the pH only increases perhaps from 6.3 to 6.7, something of that order, and if you add alkalis to raise the pH that amount, that effect is not induced at all.

Q. Excuse me; did you raise it above 6.7?

A. If you add enough alkali to raise the pH from
1464 6.3, which is ordinary farina as made normally in the household, up to 6.7, which is the pH of this new farina when it is cooked, the quick cooking effect does not take place. I mean it is not entirely due to the change in the pH value. Now, the same thing, it isn't due entirely to the phosphate, because experiments have been done with a whole series of phosphates, for instance, the tri-calcium phosphate, that is put into this new cereal, it does have an effect on the cooking, or quick cooking, but the effect is something like—I forget exactly the figures, but about a twenty-fifth as good for the same quantity of phosphate, and I do think that it is partly due to the phosphate, and I do think that the pH has an influence but these in combination perhaps plus something else, which I have not been able to detect, account for the digestion of the farina by this substance.

Q. This disodium phosphate works in partial digestion?

A. It is a chemical procedure that you can show that the starches are broken down, by physical procedures.

The ability after cooking of the material to settle out, in sedimentation tests, and a number of other tests of that sort, so that there is a breakdown of the starch and there is also a break-up of the starch, the enclosures of the starch granules.

Q. What is the pH of disodium phosphate, about 8, isn't it?

1465 A. I don't understand that question, because it depends on how much you dilute it. It is a solid chemical compound that has no pH, I would say, as such.

Q. That is right, yes, in the form in which it is added here, and in this combination, do you know the pH from the beginning of the addition until the product is consumed by the child?

A. You mean that if you have this new Cream of Wheat at the beginning of cooking, does it change from then to the end?

Q. Yes.

A. I believe that there is no change. I think measurements were made all through this, and there was essentially none, but there might be a few hundredths of a pH change, but there is essentially no change during the whole cooking process.

Q. It does ever exceed a pH of 7?

A. It doesn't get that high, no.

Q. What is the reaction of disodium phosphate with thiamin chloride?

A. Di-sodium phosphate, of course, if you have a solution of di-sodium phosphate and add thiamin chloride to it, you will destroy a large amount of the thiamin chloride, but a considerable number of tests have been made, and very many assays, biological assays have been made,

1466 on material before and after cooking, for five minutes, or ten minutes, and for many minutes more than that, and the amount of destruction of the thiamin during the cooking of this new Cream of Wheat is not detectable by biological assay.

Q. Not at all detectable, regardless of the heat or anything else?

A. Not up to 15 minutes cooking.

Q. And how do you explain that, in view of the loss of B_1?

A. It is still acid, the medium is acid, and although it is not the best pH for a thiamin retention in a food of this sort, it is apparently acid enough so that the amount of

destruction can't be measured. There is a destruction, there is hardly any doubt of it, due partly to the pH being a little bit different from what it could best be, and also because of the heat.

Q. But that amount is not measurable?

A. The amount can't be measured by bio-assay.

Q. And what of the action of di-sodium phosphate with riboflavin?

A. I don't think any tests have been done with that. Riboflavin is a very much more stable chemical substance than thiamin. If thiamin will resist a treatment of this sort, it is fairly safe as a conclusion that riboflavin
1467 would also stand that treatment, with any measurable loss.

Q. Even in this solution?

A. Even in this mixture, yes.

Q. Is there any chemical reaction between the di-sodium phosphate, and the thiamin chloride, or the riboflavin at all? Do they react together?

A. If they do, the effect has no effect on the biological value of the vitamin.

Q. If there is any molecular breakdown it is not measurable by biological means?

A. I wouldn't say if there is a breakdown, it is likely that the activity would be lost but there might be an interaction between some of these compounds, and the point I make is that if there is it does not matter since the biolocal value of the vitamins is the same.

Q. It may not necessarily be from the Vitamin B_1 or the riboflavin, if there is an inter-action, though?

A. I don't know what you mean; if you have a compound reacting with thiamin and you feed it to animals and find the thiamin is just as active as before, you as a consumer of that cereal have no care as to whether it is in one form or the other. The important thing is that it be there and have an activity.

Q. There would be some significance in the taste resulting from chemical reaction or something of that kind.
1468 Is there anything of that kind involved?

A. There is a difference in taste of this particular product, but that difference in taste is largely due to the additions of wheat germ. There is no alkalinity, no taste of the chemicals that can be detected.

Q. Well, you are using a defatted and dehydrated processed wheat germ.

Mr. Bull: Not defatted; just dehydrated.

The Witness: It is a stabilized wheat germ.

Mr. Bull: So that it won't go rancid, it is stabilized so it won't become either fatty or bitter rancid.

By Mr. Goodrich:

Q. Do you know anything about the wheat germ, this processed wheat germ, yourself?

A. What do you mean? I have seen the process, and I know how the process—

Q. What is removed and so forth? As I understood it, the wheat germ oil in the wheat germ, and the fat, had something to do with the rancidity?

A. We have two types of rancidity in wheat germ, in fact, in wheat products. One is called a fatty rancidity due to the decomposition of the oil, and the other is called a bitter rancidity, apparently due to the decomposition of maybe a protein-like substance.

1469 Now, the bitter rancidity can be prevented largely by destroying the enzymes which are responsible for the development of that, and by giving it this process, the enzymes are destroyed and therefore the bitter rancidity is avoided, and the fatty rancidity is due to oxidation, and exposure to air, and as I understand it, it is rather difficult to prevent that, because of the chemical nature of the wheat germ oil, but I think that the bitter rancidity is a much greater problem than, in the industry, than the fatty rancidity.

Q. The fatty rancidity in the germ oil is not detectable from the taste, or is that where this different taste comes from?

A. Experiments have been done—I have not had much to do with this at all, but I know that experiments were conducted on the stability, shelf-life stability, of this product, and there was apparently no measurable rancidity, under these tests, accelerated aging tests at higher temperatures, both inside the package, and outside the package.

Q. The taste from the wheat germ added to the new Cream of Wheat, where does that come from?

A. That taste is peculiar to the wheat germ. It is a nutty flavor that is rather pleasant, it isn't a rancid flavor.

1470 Q. It is not?

A. No.

Q. Your company has conducted cooking tests with this

new Cream of Wheat, and has detected no loss of Vitamin B_1, riboflavin, or iron, or calcium in the process?

A. Well, tests have been conducted, cooking tests have been conducted, and there was no loss of thiamin, there is no reason why the calcium and iron would be lost, they can't be destroyed, and no tests were actually made on riboflavin, but as I say it is reasonable to expect that it is not destroyed and all of the clinical tests, and I think that this is quite important, that all of the clinical tests were made on the cereal as it reaches the table, and not on the product as it reaches the door of the house, because during the cooking process things can happen in products of this sort that would make a substance that is perfectly fine, an iron compound that is quite available, this reaction might make the iron compound unavailable during cooking.

Q. I did not understand exactly what your animal experimentation was. Was that a digestion test of some kind, that you outlined in your original statement?

A. Referring to what?

Q. You stated that some experiments were conducted with feeding the new Cream of Wheat to animals, 1471 and then extracting it from the stomach by means of a stomach pump?

A. Those experiments were concerned mostly with whether the addition of these chemicals interfered with the digestibility of this farina, in the animal body.

Q. And the results—

A. And they were carried on with ordinary farina and the results were that there was no effect, and having those results then the same type of experiment was conducted on children, except that we did not remove samples from the stomach. It was an over-all nutritional experiment rather than a laboratory experiment on the animals.

Q. In the semi-clinical tests with medical students, did you remove it from the stomachs?

A. That work was done by Dr. Merlin, and in that case he removed samples from medical students, after they had consumed either one or the other of the cereals, and analyses were made on the digestibility of the cereal.

Q. And the results were the same?

A. The results were the same.

Q. As you found in your other test?

A. It did not interfere at all with the digestibility of that cereal.

Q. Nor did it enhance the digestibility?

A. Well, the enhancement took place before it got to the mouth of the man, during the cooking process,
1472 and after that there was no measurable enhancement.

Q. In the stomach?

A. That is right.

Q. Do you recommend the addition of Vitamin D to Farina? That has been suggested by a representative of the Quaker Oats Company, I believe.

A. I would say that there is a big problem there. We have done quite a lot of work on phosphorus, which is related to the rachiticgenic properties of cereals. It was reported originally from England. It has been fairly well proven, I think, now, that the type of phosphorus, or the type of a large part of the phosphorus in certain cereals, this type, inocite, and this phosphorus is not as available as other phosphorus.

When one does biological assays and uses a diet containing this kind of phosphorus, and the ratio of phosphorus to calcium is, we will say, 4 to 1, the actual ratio in terms of nutritional availability of the phosphorus and the calcium may be as much as 12 to 1, and therefore one gets a more severe rickets, so that it was once thought that cereals were rickets-producing because of this observation, and it has now been shown that it really is not rickets-producing. The fact is that certain of the phosphorus in the cereal is not very readily available.

1473 Now, in view of that fact, some have suggested that it might be well to add Vitamin D to cereals in order to counteract to some extent or counteract completely the effect of this unavailable phosphorus. I personally don't think that it is necessary to do that, for the reason that in the first place the laboratory experiments which have been conducted were concerned with a diet containing only cereals, and not other sources of phosphorus, usually, and that in actual human consumption of cereals, we never have that condition. In the rat it was shown that if you add Vitamin D to a diet of the type that I mentioned, you have an effect which is very much like adding more phosphorus to the diet to make up for that that is not available. I would say that if you are going to add Vitamin D that you might add it to the extent of whole wheat but not very much further, on the basis of what I have said, that the cereals are not rachitogenic has nothing to do with Vitamin D. It has to do with the availability of phosphorus in a cereal.

Q. Does Vitamin D occur in any substantial quantities in the whole wheat berry?

A. I don't believe that—I believe some experiments were done on extracted wheat berry and Vitamin D Was Found There But the Amount Is Very Small. There is another point that one might mention in regard to
1474 Vitamin D, and that is since the general population consumed such large quantities, it would be difficult to decide how much Vitamin D one should allow. In the lower population groups where more wheat is eaten than the higher groups, they would tend to get more Vitamin D, but perhaps that is all good, but it would be hard to distribute it over the population and decide whether you were feeding adults or children and I would say in order to avoid a lot of difficulty, and since there is no real basis for adding Vitamin D, that it might be well to not do so but that is my opinion.

Q. Do you think that the fortification or rather restoration as you have suggested of farina should be based on child feeding, or on its use as a general food?

A. Well, farina is often used very early in life. Some of the infants that were in Dr. Blatt's study were only three months old when they were given farina, and they did very well on that addition. It is possible to add farina in its present form to the diets of infants when they are very, very young, because it has very little bran; it is not irritating, and offers another source of calories.

Since farina is given to the very young child and even to infants, and since, for a period of several months, at least, farina and milk are the sole food of infants, it is well, I think, to pay some attention to this fact, and to
1475 supply to farina those substances that are lacking in milk, or to supply to milk those substances that are lacking in farina.

In the case of Vitamin D I think milk should carry it and in the case of iron I think that the farina would be a better vehicle for it. This does not mean, if you pay attention to infant feeding, that the farina is an infant food.

Q. No, I was talking about the basis on which we would proceed to the treatment of farina, whether we will undertake to supply the dietary of a child, or the dietary of the adult, who might also use farina.

A. Well, you will notice in the clinical work that was done, much of it was done on very young children and the reason for it was that in the very young child you can get

a much better measure, because there is not a confusion of types of foods that the children and infants are using.

The second reason, they, just like the rat, are a better experimental subject than an older person, or an adult, and I think that since the nutritional needs of the actively growing individual should be met and those needs are in general rather higher per kilogram of body weight, that one should pay attention to that and perhaps use that as a basis for enrichment of farina.

1476 Q. Restoration to the whole wheat level would take no cognizance of the differences between the child's needs and the adult's needs.

A. I think, if I understand what your question is, if you restored farina to the whole wheat levels, except in bran, that farina would be just as good, or would be a better food for the feeding of infants, than it is at the present time.

Q. Your restoration would not proceed on any differences in the requirements of a growing child and the requirement of an adult eating the same product?

A. Not if you put it on the basis of whole wheat.

Q. Is there a possibility that by adding these additional substances, you might get in farina a characteristic which would render it not suitable as a child food? In other words, the processed wheat germ, does it have its nutty characteristics, are they such as would interfere with the feeding of farina to children?

A. Well, in the work that has been done with several hundreds of infants, that has not been observed. They took the enriched farina just as well as the unenriched farina, and I don't know of any characteristic that I have suggested here that would in any way affect the liking of the infant for the food.

1477 Q. And what of the appearance of farina, after treatment with all of these chemicals? Does it look the same, and feel the same? And taste the same?

A. With the addition of these chemicals, other than the wheat germ, there is no effect, or no visual effect whatever, on the farina. The addition of the wheat germ, as I say, will change the taste, and also will give a slightly darker hue to it.

Q. Well, the ferric-phosphate, for example, what does it look like? It doesn't change the appearance at all?

A. None of the chemicals that I have suggested here have any effect on the color.

Q. And none on the texture, di-sodium phosphate?

A. That has no effect on the texture before cooking, but of course afterwards it does have an effect.

Q. That would make it easier to take, though, in the enhancement of the digestibility prior to the eating?

A. That is right.

Q. You are depending on the processed wheat germ to supply the Vitamin B, and the riboflavin in this new Cream of Wheat?

A. Well, you must remember that this new Cream of Wheat, I think the development started several years ago. At that time it was not possible to get thiamin inexpensively, and it was not possible to get any riboflavin
1478 at all, and the best thing that could be done was to add wheat germ, as much wheat germ as possible, without changing the appearance of the product too much, and the amount that is present in the product today is the amount beyond which the company does not want to go because of the change especially in the color of the product due to the addition. That doesn't mean that this amount of wheat germ does the job in restoring to farina the vitamins that it should contain, but on the basis of several years ago, it was the best that could be done.

I believe that now that prices of these other factors have changed, changed considerably, it would be in order for the development to go still further.

Q. Do you have any information as to the occurrence of Vitamin B_1 and riboflavin in the endosperm, and the several bran coats, and the germ of the wheat berry; I mean proportionately speaking?

A. I believe that I gave the values for thiamin.

Q. I believe that you did for the whole wheat berry, but I want the proportionate part in the germ, and in the bran coats, and in the endosperm, I understand the endosperm is relatively free of Vitamin B_1, that there is some information on the Vitamin B_1 content of the bran coats at least, and I don't know about the germ, and we are using the germ here and I would just like to know about that.

1479 A. Well, I can give you most of the answer to your question.

The endosperm in assays that have been made on quite a number of samples of farina contains 14 units per hundred grams. The wheat germ that is now being used contains about a thousand units per hundred grams, and the

whole wheat value I gave before, about 165 units per 100 grams.

The bran I don't have the value for, but I think I pointed out that you need about 16 per cent of wheat germ in order to bring thiamin to its whole wheat level, and that would mean that you would need 16 milligrams of wheat germ per 100 grams of flour, that would be equivalent to the amount in the bran, and 16 milligrams of wheat germ would be about 160 units per 100 grams. That would not quite give it to you; that would be 100 grams equivalent to the whole wheat berry, so that I am afraid that that figure is not good but the others are.

Q. Now, let me see, 1400 is what?

A. That is 1400 units per 100 grams, and there are 1,000 in the wheat germ, and there are 165, roughly, in whole wheat.

Q. That is 165 in the whole wheat, that is just an average figure on all of these various figures which we have?

1480 A. Yes, but the company has considerable experience on this wheat germ matter. It has been produced for over a year, or two years now, and they are running checks on the germ all the time and this value of 1,000 is fairly good for wheat germ.

Q. Is the wheat germ the best available place for riboflavin in the whole wheat berry?

A. Apparently the distribution of riboflavin is somewhat different than the distribution of thiamin. I am a little bit confused from what has been written on riboflavin as to what is really the truth in the matter. I have seen evidence, for instance, that flour contains about half as much riboflavin as whole wheat, and if that is the case, and there is only a tenth or a twelfth as much thiamin in that flour as in whole wheat, then it appears that there is more riboflavin in the endosperm of wheat, or proportionately more than there is of the vitamin.

That means that when it comes to bringing back flour to the whole wheat level, you don't have to add proportionately as much as you might expect. I mean if this data is true, and I am not certain of it, if only 50 per cent of the riboflavin is removed, you have to put back only 50 per cent to bring it up to whole wheat level, whereas if 11/12ths of the thiamin is removed, you have to return 11/12ths of it.

1481 So that there is proportionately more thiamin that has to be returned than riboflavin.

Q. If you are using a processed wheat germ for returning that, there is no way to control the amount of B_1 and the amount of riboflavin, that is all dependent on the amount that occurs in the whole wheat germ, isn't it?

A. You mean then, if thiamin is returned to the farina?

Q. Yes, in the form of processed wheat germ.

A. That is true, but when you have a large industry where there are many sources of the germ, and where there is a blending of that germ all of the time and where each batch of the germ is tested for thiamin content and blending is made on that basis, the effect, or the final result in the flour can be very well controlled, and you can very well rely upon producing a flour by this method with a thiamin content, and therefore very likely with a riboflavin content within limits available.

Q. Going back to disodium phosphate, for a minute, is there any data available with respect to the toxicity, acute and chronic, of that product?

A. Well, at the beginning, I looked up, to find out if there was any data, and I could find none, and it is reported that disodium phosphate has been found in foods as such, and therefore you might say that it is a natural

1482 chemical compound, but again on the basis of experiments that were conducted with the disodium phosphate as used here, there is no evidence whatever of toxicity.

Q. That is on the 48 infant tests conducted by Dr. Ely?

A. And the several hundred infants in Dr. Blatt's study, and several human subjects in Dr. Merlin's study.

Q. I believe in Dr. Ely's study there were 48 infants and half were fed on regular mixed farina and half on farina containing disodium phosphate, and processed wheat germ in regulated amounts present in the new Cream of Wheat?

A. Yes.

Q. And at the termination of the tests, the children manifested no differences in the number of ways that you said that they were examined?

A. That is right.

Q. Could it be that the Vitamin B_1 had no effect at all, the Vitamin B_1 and the riboflavin in the wheat germ?

A. I think that we went over that. You are asking if the disodium phosphate had an effect on that?

Q. No, I am talking about the Vitamin B-1 and the riboflavin in this wheat germ.

A. Yes.

Q. In the farina used in the test, did that evidence
1483 any effect at all in the children?

A. Well, this type of experiment was a little too short on a growth experiment of that sort, to make a measurement of that type. You just refer back to Dr. Blatt's study, where the studies were done over a year's time and growth measurements were made, and you have the answer to your question, that there was a superiority in growth and there was a trend in height, and there was a superiority in the blood, due to this mixture.

Q. Due primarily to the calcium content?

A. Due, I would say, to the mixture, the blood effect, very likely, was due to the iron and perhaps a part of the increase in height was affected by the calcium, but I would say the over-all effect was in these regards.

Q. Tri-calcium phosphate added as one of the optional ingredients in this new Cream of Wheat, does that have any alkalinity at all, does it affect this set-up?

A. If you have a solution with tri-calcium phosphate it is slightly alkaline.

Q. It is relatively insoluble, is it not?

A. It has poor solubility in water. You see, with reference to nutritional values, that apparently has no importance, because just as chalk is insoluble in water, and yet the calcium in chalk can be used nutritionally.

Q. But it would not have enough effect to throw
1484 the product over into the alkaline side?

A. A little while ago we were talking about the pH, and the effect of all of those together, on the pH, was as I said then, was 6.7. It is still acid.

Q. Has the minimum daily requirement of calcium for a child been established?

A. Well, the minimum daily requirement of calcium of a child of different ages has been estimated. I would not say that the requirements have been established, in any case.

Q. The amount up to the whole wheat level will not satisfy any of those figures, will it, restoration up to the whole wheat level will not satisfy the minimum daily requirements fixed by any of those estimates, will it?

A. Well, in one group, in one group of infants, I think

that they were, but the children two years old, the amount of milk that they eat, which, by the way is not a quart, the amount of milk that they drink is less than a quart, the amount that they were obtaining was just less than the minimum daily requirements, and it happens that the amount of calcium in this cereal mixture, in the amounts that wore given daily to that aged child, made up for that slight deficiency, and the point I make is that you can't ever say that a thing is not significant in terms of
1485 nutrition. I think that numerically it does not look important but I refuse to say that it is not significant.

Q. What property has tri-calcium phosphate which makes it where it does not interfere with the disodium phosphate, do you know?

A. Well, I suppose partly its insolubility; I don't know any other answer. Very likely there is an interaction between those two during the cooking process.

Q. And the same question with respect to ferric phosphate, as I understand your original statement, those two chemicals were selected because they acted well in conjunction with di-sodium phosphate, and did not interfere with its action?

A. Phosphate compounds, all of them were phosphate.

Q. And then if di-sodium phosphate is allowed as an optional ingredient in farina, the iron and calcium additions are to be allowed, those additions would have to be made in the form of ferric phosphate and tri-calcium phosphate?

A. Well, I am only talking in terms of what I know about these compounds. You see, we have the data that if these compounds are used, and if farina is cooked with these compounds in it, and then this farina is fed to experimental subjects, it is possible to demonstrate that the cal-
1486 cium is retained, and that the iron is available and that the disodium phosphate exists in the digestion and that it does not interfere with the wheat germ.

Now, that does not mean that disodium, or that for instance, di-calcium phosphate, would not be an allowable substance in farina. I would say that it is likely that it is, from the work that I know, that has been done on the retention value of di-sodium phosphate, but in this particular circumstanges we have the demonstration that these compounds together do a job and do it well, and therefore it seems to me that they should be allowed.

Q. Well, if we are to allow the disodium phosphate and also calcium and iron additions, it would not be safe to allow any calcium or any iron addition in view of the information which you have, and in view of your recommendation that these two products be allowed because they act well in conjunction with disodium phosphate, is it?

A. I would say it is not safe to allow any substance of this kind until it has been shown first that it is not toxic, and second, that the mineral or vitamin is available and does a job as good as something else, in comparison with something else that is known, and I think it is very important that one demonstrate not only that it is present and not only that it is non-toxic, but also that it is effective, before it is allowed.

1487 Q. And in your case, also, that it acts well in conjunction with disodium phosphate, which is added for its cooking value, is that not true?

A. Well, I don't mean to say that if you use dicalcium phosphate in this preparation, instead of tri-calcium phosphate, that it would have an effect on the availability of the calcium. I don't know, it may or may not. The only point is that when these are put together this is the result, and it is important that you know when they are put together that you do get the result before they should be allowed in use.

Q. Would it be in the interest of consumers, and would it promote honesty and fair dealing in the interest of consumers, to permit mono-calcium phosphate, and ferric oxide, or something of that kind, as the calcium and iron products in connection with a farina which also had added to it for cooking values, a disodium phosphate?

A. You asked several questions there. I don't think the disodium phosphate has any real effect on the availability of iron or the calcium. There is no evidence here in comparison with other work that has been done, that the disodium phosphate has an effect on these availabilities. If it is present in large amounts, and tends to increase the pH of the gastro-intestinal tract, perhaps it might interfere with that availability, so that if ferric

1488 oxide were allowed, it might or might not be important that you specify that disodium phosphate not be present; I don't know.

Q. In other words, all of your testimony with respect to disodium phosphate, tri-calcium phosphate, and ferric

phosphate, is dependent upon the use of the three in combination, and not on the use of any one alone, or not on the use of ferric phosphate alone, or tri-calcium phosphate alone but their action in connection with disodium phosphate, is it not?

A. Well, there are two things one could do on a subject like this. You could take calcium phosphate and iron phosphate, and do experiments, this sort of experiment has been done, to measure the availability of these metals and then having done those experiments you put them together in a cereal of this type, and you have to repeat those experiments.

Q. Well, what information have we with respect to the cooking value of disodium phosphate when some other iron compound, other than ferric phosphate, is used for that purpose? Will you or will you not have a reaction between the iron and the disodium phosphate when the iron is put in, in some form other than ferric phosphate?

A. I couldn't answer that. There is a possibility that there would.

1489 Q. And I suppose the same is true with respect to some calcium combination other than tri-calcium phosphate, apparently Arthur D. Little & Company selected those because there was no inter-action between them; from your original testimony, I believe that you said that they were selected because they acted well in connection with disodium phosphate.

A. And plus other reasons, for instance, the tri-calcium phosphate has a lot of calcium per gram of phosphate, and in a product of this sort you want to keep the chemical content down.

Q. That would be the nutritional advantage.

A. You see, the proof of the pudding is in the eating, and as I pointed out, you have several ways to go at a work like this, you can take each of the things that might be used, and find out what they are good for, and then you have to put them together, and after they are put together it is necessary that you do it all over again.

Now, a company of this sort, it already costs many thousands of dollars to do what they have done, but in order to answer this question, you would have to repeat it with a whole series of compounds before they are put together.

Q. You would not recommend that a product of this

kind be placed on the market for consumption by
1490 human beings unless that experimentation had been done, would you?

A. And not until it had been done, and they have been put together and have been cooked, if the product had to be cooked, had been cooked and then the measurements were made on the availabilities.

Q. What is your idea on fortifying staple American foods with special reference to a selection of those foods? Do you have any plan or are you aware of any plan formulated by nutritionists as to what foods are included within the designation of staple American foods?

A. I know several groups that are at least considering this problem. I think that we have to list as staple foods, cereals and cereal products, refined cereals and refined cereal products.

Q. And that is all of those products?

A. All of them, yes.

Q. Even farina, and semolina, and those products?

A. I think all of them that have been refined should be made unrefined again. We have been taught to think that refinement is a very important attribute, but in the case of foods it is not.

The second is undoubtedly sugar. I think macaroni and that type of product, I believe that is all covered by cereals. I think that some fats, especially the margarine type of fat, should contain the vitamin and mineral
1491 values, if there are minerals, of the type of fat for which they are substituted.

Q. Then at least your designation does include farina?

A. Yes, I am heartily in favor of enriching farina. In fact, that is what attracted me to this whole problem.

Presiding Officer Willcox. We will take a few minutes recess at this point.

(Recess.)

1492 Presiding Officer Willcox: We will continue, then.

By Mr. Goodrich:

Q. All of your testimony relates to farina, as used in breakfast food form, does it not?

A. That is right, I think, yes, I would say so.

Q. Now, the optional ingredients which you have mentioned would have some effect on the usefulness of farina as an ingredient in macaroni and noodles, would it not?

A. Oh, yes, it would.

Q. And what effect would those recommendations have, those recommended optional ingredients have?

A. If it were put in noodles, assuming that the heat treatment that you give noodles would not do something to one of these constituents, and I don't think it would, then the noodles made with this formula would be quite as good as Cream of Wheat, as far as the availability of this is concerned.

Q. What about the action of di-sodium-phosphate in the preparation of noodles, wouldn't that begin the process of digestion, and render the farina altogether unsuitable for use in the preparation of macaroni and noodles, where a certain degree of firmness is desired?

A. I don't know much about noodles manufacture
1493 I was thinking when I answered your other question in terms of the other constituents. In the manufacture of noodles, I would say that it is likely that perhaps you wouldn't want to add the disodium phosphate, and there is one thing that I have been trying to make clear, and it keeps recurring.

I am taking a very accurate scientific position in saying that when it is put in this form, and the measurements are made in this form, these are the results that we get. That is the thing we know. But I am not saying that if you took these substances in different amounts, or if you used other substances than these, in a farina, that these same results might not be obtained. The point is that we have not made a demonstration of the other, but we have made a demonstration of this peculiar combination.

Q. And from your demonstration, the resultant farina is after cooking, a very much more finely granulated substance than it is without the addition of disodium phosphate, is it not?

A. If you cook farina for five minutes, or if you heat farina for five minutes, it isn't cooked; if you add the disodium phosphate it is cooked, and the farina at the end of five minutes cooked with disodium phosphate is essen-
tially of the same degree of cooking as farina with-
1494 out the disodium phosphate cooked for thirty minutes or more.

Q. Well, that is due to the disintegration of the carbohydrate and some of the protiens in the cooking process, where you have this disodium phosphate added, is it not?

A. It is due to the breakdown of the little capsules in which the carbohydrate is contained, and also to a partial breakdown of those carbohydrates, and also it is perhaps a denaturation of the protien during that process.

Q. Do you know whether or not that condition is desirable in farina for use in macaroni and noodles?

A. Well, that is all that happens when you cook farina, and I mean that what has happened here is that it has been catalyzed, it happens in five minutes instead of thirty, and you are asking is it desirable to cook farina, and I say "yes."

Q. I am not exactly asking that. I want to know what the effect of this addition of disodium phosphate would be on farina when that farina was used in the preparation of macaroni. Now, I don't know whether you cook farina for thirty minutes or for five minutes in the preparation of macaroni, I just don't know that, I am sorry, or you might not cook it at all, and make it up into a dough,
1495 and whether or not that disodium phosphate is desirable in the preparation in farina, for the preparation of macaroni and noodles, I don't know, and I would like to get that information from you.

A. Well, that is something, to a noodle manufacturer it might not be desirable because it may change the texture of the noodle or something, I don't think it would, but as a nutritionist I think it is desirable that you digest the starch, or breakdown the starch by some process, and this is an accelerator of that breakdown, and whether it is desirable for the noodle manufacturer to use disodium phosphate, I would say that I am not qualified to say, because he has certain characteristics that he wishes in noodles, and they have nothing to do with nutrition.

Q. One of those characteristics apparently is that in the cooking process that not be the breakdown which is desirable in farina for use in breakfast food, is it not?

A. I don't know about that.

Q. Would it be desirable from the standpoint of a consumer planning a diet to recognize farina which had not been fortified as a separate product from a farina which had been fortified in the way that you suggest?

A. I think it is desirable to let the consumer know
1496 what good a food is, and if you have improved a food it is very desirable that you let the customer know that that improvement has been made.

Q. And that improvement would make it a different

product from the farina which had not been treated with those chemicals, or with the vitamin and mineral additions?

A. I wouldn't say that, because it is my point that farina, what is farina has been changing all of these years, and I am only suggesting that you put back into farina what you might call farina of the old days, what it had in it already, not in exactly the same chemical compounds, but with essentially the same nutritional substances.

Q. Then is it your idea that the farina as it exists today is not really farina, but is some offspring which we ought to get rid of and go back to the old days?

A. Well, that brings up a question, I am not a cereal chemist, the dictionary tells me that farina is the endosperm of hard wheat, and now if you took hard wheat in 1850 and ground it and tried to get the endosperm out and took the grindings and sieved them through a cloth, what came through that cloth would be farina, in that sense. It is different from the farina today because we have done lots of other things to farina to make it.

1497 I am saying that just as we talk about a cereal, a cereal today is different from a cereal of the old days, and in fact we have so many kinds of cereals, so many degrees of purity, that we talk about whole wheat cereals and fine cereals, and we have to use adjectives to describe these differences, but they are all cereals, and I say that farina, the chemistry and composition of farina in the sense that I have defined it has changed during these years, and what might have been, I am not sure it was called farina in 1850, but what might have been called farina in 1850, and what we know as farina today is a different product in that sense, but it is essentially the same thing, only at that time it was less pure—or rather was a better nutritional substance, in the sense of refinement it was less pure.

Q. If we are to retain on the market today a farina as some people know it, and we are to put on the market today a farina equivalent in nutritional value to that which would have been farina had it been produced in 1850, are those two products different to such an extent that the consumer should be apprised of that difference, in purchasing them?

A. I could make a farina with the potency of 1850 farina, that the customer would not recognize by her eye, or by her taste, but it would contain essentially all

1498 of the important nutritional factors of that farina.

Now, your question is, should the customer be told

that I put it in there, and I of course have said before that she should.

Q. And the difference in the nutritional value of the two products is such that there is enough difference in them that the consumer should be apprixed of that difference?

A. I believe that the consumer should, the question of course is how to apprise the consumer. I believe that we are trying to apprise the consumer thinking the consumer is a home economist, or someone of that training, and not thinking of the consumer as being a person of rather poor education, of little realization of all of these nutritional things, and by telling how many units there are or perhaps even what proportion those units are of the day's requirements, I am afraid that lots of people that I know will miss the point; but if you tell them that by putting thiamin into farina to bring it to this 1850 farina level, tell them that that was done, and tell them that that now makes the farina an excellent source of thiamin, and then the lowest person in the population will have some comprehension as to what that means.

Q. But would a person know that there was any substantial difference between a farina just called farina, 1499 and one called old-fashioned farina?

A. Well, I am not a Government authority on that sort of thing, but the point is that if you have farina labeled, and you say that 1938 farina is a poor, or only a fair, or let us say a poor source of thiamin—

Q. Nobody is going to label it that way, we have no authority in the world to require them to do so.

A. But you are asking the question, you can tell the customer by saying that this farina is a poor source, and that farina is an excellent source, and then the customer knows what has happened.

Q. Under the Federal Food, Drug and Cosmetic Act, we have no such authority, maybe fortunately for some and unfortunately for others, but we have not that authority, and we have to proceed in the best way possible.

Now, is it your idea that the farina that is on the market today should be recognized as one subject, or one product, and a farina with important nutritive additions should be recognized as a different product, in order to promote honesty and fair dealing in the interest of the consumers?

A. I think that—I don't know exactly what is behind the question—but I think that, or I would say that if you are going to take a very poor food and make it an excel-

lent food, the public has to know that it has been made
1500 very excellent, and perhaps the best way to have the public know that it is excellent is maybe to call it something different, I am not sure about that.

I do think that there is benefit in letting the customer know it. Now, the trouble this morning, there was a remark made that the consumption of flour in this country has gone down considerably in the last forty years, and I think to no small extent that consumption has been due to groups such as individuals such as myself, and people also in home economics, instructing their staff, and advertisers telling the public that these refined cereals, these refined flours, are poorer, the protiens of cereals are not as good as the proteins of something else, and the public has been more or less frightened away from the consumption of cereals on the basis of this, and it is my point that the milling industry—not of its own knowledge—has been ignorant of the fact that what has happened to flour in the last forty or fifty years was a very bad thing, and part of the consumption of wheat, the poor consumption of wheat in comparison with those of past years, is related to the fact that the public are conscious of the fact that these cereals and these flours are poorer as food substances than some other food that they might consume.

And if you want to win back the market, a serious
1501 attempt to make these cereal products as good as they were, would do a lot in that direction.

Q. Isn't it your idea that something has been substituted in the American dietary for wheat products, by consumers in an effort to obtain an adequate supply of Vitamin B_1, riboflavin, calcium and iron, which have been removed in the milling process of wheat?

A. Why, yes, the dietary has changed, maybe consciously or unconsciously. The public have been told either directly or indirectly that, we will say, flour is deficient in some things, and if you want to get the things that are missing from flour you must consume other foods such as green vegetables, and fresh vegetables, and there has been a definite change in the habits of the population.

Q. And you attribute that to this refinement which has removed from the wheat berry valuable nutritive elements?

A. No, I attribute it in part to this fact.

Q. In your testimony with respect to New Cream of Wheat, you set certain limits on the ingredients therein and we would like for you to state for the record the mini-

mum and maximum limitations on the ingredients which you have suggested, and which you consider significant in the farina which is a special product.

1502 Presiding Officer Willcox: That is to suggest minima and maxima that might be prescribed in a standard of identity?

Mr. Goodrich: Yes, sir.

The Witness: I had not thought of it in terms of that, and perhaps you see, I should make no off-hand suggestion of that, because it is rather a serious thing to do. You will notice that the materials that were added in this product were in amounts that usually brought it up to a whole wheat level or something approximating that, with the exception of iron, and the reason I gave for that, and with the exception of wheat germ, and the reason I gave for that, I mean there is three times as much or four times as much, or two to four times as much wheat germ suggested there as is present in whole wheat, and the reason there is more is because an effort was made to increase the thiamin content of the final mixture by so doing.

I would hesitate to put the top, to be consistent you might put the top at the top level for wheat, whole wheat, and I think it is necessary that you have enough there so that the demonstration can be made, the demonstration in infants can be made that the amount present has an effect.

If you want later, I can send in an estimate, but I
1503 think that it would be a mistake to try to do it off-hand right now.

By Mr. Goodrich:

Q. Well, you have recommended the addition of tri-calcium phosphate, ferric-phosphate and wheat germ, processed wheat germ, and that to include thiamin and riboflavin, and you recommend that the additions be to such an extent that you build it up to the whole wheat level.

You make an exception on iron phosphate, to get an additional amount of iron, is that right?

A. I made an exception on iron.

Q. You made an exception on wheat germ because you want to get a little bit more, or a specified amount of thiamin and riboflavin, in this wheat germ, and that only leaves tri-calcium phosphate added up to the whole wheat

level, and the testimony is that the calcium in the whole wheat level is rather insignificant. Is that your position or not?

A. My position is that those who manufacture farina should be allowed to add those substances which are present in whole wheat, and which are not present in farina, or are present in smaller quantities. That is not really the chemical substance that is not present, but an equivalent of that chemical substance.

It might be advisable in the case of wheat germ
1504 to add only two per cent wheat germ to bring it up to the whole wheat level, and then make up for the other factors by adding synthetics, and it would seem, however, a little bit more desirable to add more wheat germ since it doesn't change the characteristics of the farina.

I admit that I seem to be jumping from one side of the fence to the other on this thing, and I think that at the present state of this whole thing we have to do a little bit of mug-wumping on it, but I think as a general place to start it is to go to the whole wheat levels and if you have a reason that can be defended, to raise it above that level, then I think one should be allowed to do that.

Q. Is there a valid reason for building the calcium up beyond the whole wheat level?

A. I don't think so, but in a meeting that I attended here a couple of weeks ago, it was pointed out that in respect to Southern wheat, calcium is added there for another reason, and if you say that calcium shouldn't be added to whole wheat, there are circumstances, for instance the South, where it should be added to whole wheat.

That is why I think that you shouldn't assume that it is insignificant, the amounts should vary according to the conditions. But I point it out, already, that there is a large amount of calcium in milk, and if the person
1505 is consuming milk then the amount of calcium here is not significant. However, if a person is not consuming milk, then the amount of calcium here might be very significant, because a person on a diet that does not contain milk at all, in any form, is usually on calcium starvation.

Q. If he were consuming a product with a calcium content built up on the level of whole wheat, he would still be on calcium starvation, would he not?

A. But he would not be starving quite as much, and it would be very significant from a physiological point

of view, a small amount would be very much more important than you think.

Q. He still would have a deficiency of calcium?

A. Yes.

Q. Your idea is that you in no instance want to go below the whole wheat level, and anything that you can do to build up these nutriants is better than nothing at all?

A. That is exactly what I would like to say, that the least we can do, the least the milling industry as a whole can do is bring it to the whole wheat level.

Q. But if they are going to do anything, the more plausible thing is to do something which will have a significant effect in building up the American dietary, is it not?

1506 A. That is right.

Q. And this is the very, very minimum?

A. What was said this morning, suggesting that thiamin be added, is a very laudable position to take, but I disagree with taking the position that that is the only thing that should be done. And I also disagree with the position that that is the only thing that can be done today, and there is where the debate comes.

Q. To carry your position forward, you would recommend Vitamin B, because that is something better than they are doing now, but that you would recommend in addition to that that they do more because they can do more, and it would be in the interest of the consumers that they do more.

A. That is right.

Q. You would rather not suggest any minimum or maximum figures for these?

A. Well, why don't we suggest the minimum of whole wheat, and the maximum where it would be proper. You see, the trouble with the maximum is that there are conditions where if you put the ceiling too low there are conditions where there would be an interference from making a good food for a special purpose, for special reasons, and the trouble with putting the maximum too low is that it would tend to cut down the broadening of the dietary,

1507 the enrichment of the dietary.

Q. Putting the minimum too low you would get by with doing a little bit, and not doing enough by reason of an allowance of a calcium addition away below the

amount required by a human being in his daily food in-take?

A. Of course, in nutrition, we have no real patience with the term "minimum." Minimum is a term that is invented perhaps for legal reasons, in order that you may be able to enforce some position, and minimum requirements.

Q. You make any suggestion you want, and if you don't like minimum or maximum, and you want to make some suggestion, we would have you go ahead, and we would be happy to have it in the record, and we would like to know the basis on which you suggest it.

A. That is why I prefer not to make it now, but if I can do it later that would be very much better.

(Whereupon, the then following discussion, by the direction of the Presiding Officer, was not placed on the record.)

Presiding Officer Willcox: If Dr. Harris can make any such suggestions, in time that they can be incorporated into the record, and given to us so that other people will have an opportunity to comment on them, they will be accepted.

Mr. Goodrich: That is all of the examination I have.

Presiding Officer Willcox: I would like to ask one or two questions of Dr. Harris. I was struck with the fact or by the fact that apparently in those cases where the entire diet is so to speak under control, such as with the Anartic Expedition, and to a certain extent the diet of infants, you seem to approach this question from the standpoint of the need of the individual.

The Witness: That is right.

Presiding Officer Willcox: And I was wondering whether that indicates that you consider that the better approach, where practicable, and that you used the approach of a natural product only in default of a better one, where the diet you feel is so uncertain in its make-up that the approach of nutritional requirements is impracticable—is that a fair statement of your position?

The Witness: I would say that if you can treat an individual as an individual subject, and be able to study them, as to their size and sex and shape, and how they handle foods, and make a series of measurements on the amounts of different nutritional substances they require to stay in balance, either nitrogen balance or vitamin bal-

ance or mineral balance, that doing it that way you can treat the subject as an individual and take care of his individual needs.

1509 In the case of the Expedition, the men are generally of the same type, they are more or less of the same age, in fact within ten or fifteen years, and you can treat them more or less as an individual. In a clinic, a pediatrician with a group of infants under his control, each infant that he feeds receives a different amount of food according to the way in which that infant is developing, and according to its age, and so forth.

But when you get into a big population group, where you have all ages and all conditions, then the problem is very extreme. If you try to average the whole population, and treat the population as one individual in the middle of that age, or that average, you will make a mistake, and it seems in the case where you are feeding the population the important thing is to either take an individual whose requirements are above that average, say 50 per cent above that average, and assume that what will take care of that individual will take care of the population as a whole.

Or else attack the problem from this point of view: On the theory that an unrefined diet can be made quite adequate for any individual, and that if we make a refined diet to simulate the unrefined diet, then the nutritional problem would perhaps be solved; so that there are two approaches, and it depends on the circumstances.

1510 You can either treat the population as an individual, an individual that is 50 per cent higher than the average, we will say, in his nutritional needs, or else you treat the population as an experimental animal, on all kinds of diets and have an unrefined nature, and assume that by chance this individual will get all of the nutritional substances that he needs.

Does that answer your question?

Presiding Officer Willcox: I think it does, with this question: Would you say that the latter approach is—you said it is dictated by certain assumptions—that it is taken as rather a practical way out because of the impossibility of individual analysis of all of the cases that you would have to deal with?

The Witness: That is right, it is only a practical solution, the better method would be to be able to analyze

every person's need, and every circumstance, and treat his needs as an individual. Since that is impracticable, perhaps this is the better way out.

The difficulty of these minima are that this individual that I have mentioned is getting 50 per cent more than those minima, and by doing that it may sound to be extravagant, but in terms of nutrition it isn't.

I know that if you talk with the general public, and I have talked with them a lot about this question of
1511 minima, that they assume that the minimum is what they need, in order to be very well fed, and that of course isn't what is meant by the term at all.

Presiding Officer Willcox: Do I understand from what you say, that the minimum requirements, using that term in the sense that you are using it, as I understand, vary widely among different individuals, even in cases where you couldn't say that there was any marked deficiency?

The Witness: Oh, yes, and extremely wide variations, we can't produce vitamin D deficiency in infants, in certain infants, and in other infants you can produce it even though you give Vitamin D to them. There is a very extreme variation in the requirements of individuals for each of these substances.

And even though a person is eating 50 per cent more than what appears to be the minimum requirements, that individual may still have a deficiency, because his requirements may be four times what this average individual requires.

Presiding Officer Willcox: Are there any other questions of Dr. Harris on cross-examination?

Mr. Gilbert: There is just one question that we have here.

1512 *Cross-Examination by Mr. Gilbert.*

Q. Dr. Harris, I don't know whether you want to talk on this little point. As you probably know, the proposal for farina sets the ash at some figure to be within a range of 0.45 per cent to 0.65 per cent.

As I understand it if you would add these additional ingredients to which you refer, that would result in the ash content being increased over the highest figure mentioned. I was wondering whether you know whether it is the position of the Cream of Wheat Corporation to request a higher maximum ash in the event that these other ingredients are included?

A. It seems to me that if by the addition of important nutritional substances, we change the ash content so that it doesn't come under a specification, then that ash content should be changed. After all, I understand that these ash contents are stated for purposes of regulation, and I don't think that regulation should at any time interfere with the proper nutrition of the public. And if the regulations as in this case interfere in any way, I think that the regulations should be changed.

Presiding Officer Willcox: Are there any more questions on cross-examination? Will you give your name, please?

Mr. Frohring: Paul R. Frohring, appearing in 1513 behalf of General Biochemicals, Inc.

Cross-Examination by Mr. Frohring.

Q. In your testimony this morning you enumerated some various vitamins found in whole wheat. Isn't it a fact that whole wheat also contains carotene?

A. I didn't mean to testify that that was all that was present in whole wheat, there is carotene there, several forms of carotene, I believe, and there are other vitamins besides those that I mentioned, and there are perhaps vitamins that I didn't mention that nobody knows about.

Q. Well, you enumerated quite a long list, and they are mostly the vitamins in the Vitamin B Complex, and since Carotene was not mentioned I wanted to ask that question.

A. Yes.

Q. The literature shows the carotene content in whole wheat flour from 194 to 456 gamma per hundred grams. Assuming that these figures are correct, it indicates 300 gamma as an average, that would be equivalent to about 2,000 International U. S. P. units per pound of whole wheat flour. In your opinion is this significant as an amount of Vitamin A activity for a natural food?

A. Yes, that is a significant amount.

1514 Q. Is carotene destroyed or lost by present milling methods, and bleaching and so on?

A. I understand that carotene is completely destroyed during the milling process.

Q. Well, then, based on your restoration principle, in your opinion since carotene is a natural constituent of

whole wheat, and is destroyed by processing, should it not be included as an optional ingredient to flour, just as the others?

A. Well, I think that I have taken care of that question, by saying that it is my opinion that all of the nutritional substances in whole wheat, important to human beings, should be returned to flour or other substances, at least to the extent of whole wheat, and that would include Vitamin A.

Q. My reason for the question is that the other vitamins were mentioned by name to be included, in the original testimony.

A. I think that I have pointed out that what I requested as optional ingredients was in behalf of a particular company.

Q. I see, that is all.

Cross-Examination by Mr. Thode.

Q. This morning I think that you testified or com-
1515 mented on the general effect that there is a need for supplying Vitamin B_1 in sufficient amount to care for the metabolism of the caloric in-take. Could you express that view in terms of the ratio of B_1 units which should be needed, which should be supplied per each 100 calories of in-take?

A. There is considerable discussion in the literature as to what the ratio of thiamin should be in terms of calories. These estimates range from something around five units per 100 calories, up to I think thirty units per 100 calories. I would say that the best estimate of that, and of course they are still estimates, the best estimates are that the requirements are maybe 15 to 20 units per 100 calories.

Q. That is per 100 calories?

A. Yes.

Q. Have you any view, or do you know from experience what caloric in-take is in the average balanced daily diet?

A. Well, the average, I have pointed out, doesn't mean very much. In most calculations the average is assumed to be about 3,000 calories. I believe that this 3,000 calory value is, if anything, a little bit modest.

Another point is that especially in lower income groups
the calory requirements tend to rise somewhat above
1516 the average for the population, and cereals are consumed in larger amounts by this particular group.

so that I would say that 3,000 might represent what might be called the minimum, as an estimate, and somewhat more than that could be the optimum.

At one time I looked up this matter, and as I remember it, it was perhaps 3600 calories for this lower income group would be more, or a better estimate of the calory in-take.

Q. That is all.

Cross-Examination by Mr. Logue.

Q. Would you care to state the preferred form of the iron phosphate? You mentioned ferric phosphate, but would you care to answer that?

Mr. Bull: I will object to that question. I would rather that question didn't come out, for competitive reasons.

Mr. Logue: If he doesn't care to answer that is all right. There is subsequent testimony that might have some bearing one way or the other.

Presiding Officer Willcox: Do you want to press that point?

Mr. Logue: I won't press it.

Mr. Goodrich: The form can be determined by 1517 simple analysis, can it not?

The Witness: Yes, it can, but when you get through cooking Cream of Wheat it is not necessarily in that form.

Mr. Goodrich: I mean just taking an analysis of Cream of Wheat before cooking, you could determine in what form the iron was in, whether it was ferric-othophosphate or ferric-pyrophosphate, couldn't you, and if so I would like to have the question answered, so that we will have it in the record. I don't want to require the divulging of any trade secrets.

Presiding Officer Willcox: Unless you have any particular reason that you think it important, I think we will leave it out.

Mr. Goodrich: I think it probably would be important for making a complete record, but I don't care to make them divulge any trade secrets. My idea was that if it was a fact easily determinable by simple methods of analysis, it would not be requiring the divulging of any trade secrets here. He tells me that it would be, so on that basis I don't care to insist on it going into the record.

The Witness: It may be that the questioner was trying

to find out what kind of iron one used in a food of that sort, is that the question?

1518 Mr. Logue: I will withdraw my question. I don't wish to embarrass anyone.

Presiding Officer Willcox: Is there any redirect examination?

Mr. Bull: Thank you, no.

Presiding Officer Willcox: Is there any further questioning of this witness?

Mr. Goodrich: I have no questions.

Presiding Officer Willcox: I think that we will adjourn now. Do I understand that the Millers National Federation wishes to adjourn through tomorrow morning?

Mr. Goodrich: Is there any additional evidence that we can proceed with while you are meeting tomorrow morning, or do you care to be here during the whole time. Perhaps there is something that we could take up probably in the morning while you people are meeting on the vitamin problem.

Presiding Officer Willcox: I don't think that there is anything that we can properly take up, I assume that most of the National Federation witnesses will be at that meeting, and I don't believe that there is anything that we can take up properly tomorrow, is there?

(Whereupon, the then following discussion, by the direction of the Presiding Officer, was not placed on the record.)

1519 Presiding Officer Willcox: We will adjourn until two o'clock tomorrow afternoon.

(Whereupon, at 4:30 o'clock, p. m., the above hearing was adjourned, to reconvene again the following day, November 13, 1940, at two o'clock, p. m.)

1523 PROCEEDINGS.

Presiding Officer Markel: The hearing will please come to order.

We now have here some additional appearance blanks for the use of anyone who has not already filed an appearance in this hearing, and I might say that there seems to have been some misunderstanding. It is not necessary for anyone who filed an appearance at the original hearing, in September, to file a new notice of appearance.

I have here two affidavits which have been received by mail, one by Dr. Harry Steinbach, and the other by Mr. J. P. Hubbell. The latter of these has not been sent in with sufficient copies and will have to be completed but these will be available for anyone here who wants to look at them before they are introduced in evidence.

Mr. Goodrich: With respect to the affidavit filed by Mr. Hubbell, I suggest that his attention be called by letter or otherwise to the vagueness of his affidavit and to the fact that it will not be considered for any substantial purpose in view of his failure to explain exactly what his ingredient was. I suggest that you write to him some time during the hearing, today or tomorrow and ask him if he can arrive here if he would care to before the termina-
1524 tion of the hearing. It is just a suggestion.

Presiding Officer Willcox: I will consider that in connection with the additional copies.

Mr. Campbell: I would like to call Dr. Bailey. Whereupon

DR. C. H. BAILEY, was called as a witness by the Millers National Federation, and having been first duly sworn, was examined and testified as follows:

By Mr. Campbell:

Q. Dr. Bailey, will you please state your name, residence, and occupation or profession?

A. My name is Clyde H. Bailey. I am Professor of Agricultural Biochemistry at the University of Minnesota.

Q. How long have you held your present position?

A. I came to the University of Minnesota in 1911 as an instructor and have advanced through the various academic grades in the intervening twenty-nine years.

Q. Will you proceed in your own way and explain what your educational qualifications are, and your past experience, and so forth?

A. Well, I have a Bachelor of Science degree from the North Dakota Agricultural College, Master of Science degree from the University of Minnesota, and Doctor of
1525 Philosophy degree from the University of Maryland, and my first professional services or activities were with the U. S. Department of Agriculture, in the Bureau of Plant Industry, until 1911 when I came to the University of Minnesota. During the intervening 29 years, in addition to

my connections with the University of Minnesota, itself, I have at various times occupied certain other positions, including the Directorship of the Technical Bureau of the Biscuit and Cracker Manufacturers Association, the Directorship of the State Experimental Flour Mill or Testing Mill, as it is called, and for a time served as Director of Research for one of the larger milling companies.

As a member of the Experiment Station staff in the faculty of the University of Minnesota I have been practically continuously engaged in the researches in the field of cereal technology and related biochemical investigations, and I have published, either as author or joint author, somewhere between 250 and 300 bulletins and articles in scientific technical journals.

I am the author of a technological monograph of the American Chemical Society, entitled "The Chemistry of Wheat Flour," and of a monograph published by the Food Research Institute on Physical Tests of Flour Quality.

My investigations have covered a wide scope and involve rather close relations with the milling and baking and
1526 related industries, as well as wheat production.

Q. Now, you are familiar with the issues that are being considered in this proceeding, are you, Doctor?

A. In a general way, yes.

Q. Will you proceed in your own way to make any statement that you desire, that is pertinent to the issues in this proceeding?

A. I am not a specialist in the field of nutrition, or physiology, but wish to refer more particularly to some of the technological aspects of milling, and perforce of baking as well, in its relation to the understanding of nutritive properties of different flour types, or grades, and in opening that phase of the discussion I would like to refer first to the chart here at your right, which represents a kernel of wheat.

Mr. Goodrich: Doctor, do you have copies of that for introduction into the record? If so I think it would be proper to place those in the record. I think it would be well to place them in the record at this point if you have them.

Mr. Campbell: I think that we can do that.

The Witness: We will make them available.

Mr. Goodrich: Here is one right here. Can we have that marked here?

Mr. Campbell: I offer the chart which has a cap-
1527 tion "A kernel of Wheat" about which Dr. Bailey is speaking, as Millers National Federation Exhibit "P."

Presiding Officer Willcox: If there is no objection, it will be received and so marked.

(The document above referred to was received in evidence, and marked MILLERS NATIONAL FEDERATION EXHIBIT P.)

The Witness: Now, for purposes of this particular discussion, the kernel of wheat may be considered to consist of three major structures, or groups of structures:

First, the outer pericarp, consisting of several layers, which in so far as the development of the kernel are concerned are in reality the residues of the wall of the ovary in which the wheat kernel develops or grows. Within them are other fibrous layers consisting of the various structures of the testa, or seed coat covering, specifically. As a matter of fact, the wheat kernel is a fruit rather than a seed to the extent that the ovary wall which is somewhat analogous to the pod of a bean or pea, is fused to the seed proper.

Incidentally, it is interesting to note that one of these layers of the testa is heavily pigmented in the instance of the red wheats and it is the transmission of the colored pigment from that layer out through the pericarp what gives rise to the coloration which is characteristic of those types of wheat.

1528 Second, I will refer to the tissues of the germ or embryo, a rather complex structure situated at the lower end of the kernel as it is borne in the head, and providing or consisting of the rudimentary plant parts which appear in the seedling stage, when germination ensues.

Now, the pericarp and adherent layers of the testa constitute in the range of 14 per cent plus or minus of the weight of the grain. The germ embryo constitutes about 2½ per cent, on the average. The percentage, of course, depends upon the relative development of the grain in its later stages of maturation.

Then you have this large endosperm structure consisting of two major types of material, the endoryn, and the starches and aleurone cells specifically, representing in the usual well-filled wheat grain roughly 84 to 85 per cent by weight of the grain.

Now, a pericarp, and adherent testa, or what we may for

convenience refer to as the branny layer, is characterized by a high content of cellulose and pentosans, generally regarded, I believe, as essentially non-digestible, not utilized in human metabolism.

In the life of the plant, it serves as a protective organ. Its function is essentially to envelop and protect the more delicate tissues of the embryo, and the storage reserves in the endosperm.

1529 As far as the chemistry of the germ is concerned its most characteristic chemical constituent in point of quantity and distinctiveness is a relatively high content of oil, and of sugars, although unlike the adjacent endosperm it does contain appreciable quantities of nucleo proteins.

The constituent of the endosperm is starch in point of quantity, roughly 70 per cent of the normal endosperm consists of starch.

The percentage varies inversely as the percentage of gluten. Associated with the starch but in smaller quantities, to be sure, are the proteins which comprise the gluten, which imparts the characteristic physical properties to doughs made of wheat and wheat flour.

Now, with regard to the dietary accessories to which I have not referred particularly heretofore, and referring back to the germ or embryo, this is very rich in thiamin or B_1, 8 to 11 international units per gram, probably representing the range of the majority of samples. I don't represent that those are the outside limits, necessarily, but probably most of the specimens would fall within that range, and also doubtless rich riboflavin, sometimes known as B_2 component of the B complex, and the oil of the wheat germ is, to be sure, a conventional source of the reproductive vitamin or Vitamin E, and is used in medication not infrequently for contributing that vitamin to a diet.

1530 Due to the fact, however, that the germ or embryo represents a relatively smaller percentage by weight of the entire kernel, the actual amount of B_1 in terms of the entire grain which is in the germ is relatively small, probably about one-sixth of the total B_1 of the entire grain will be found in this tissue, as nearly as we can estimate from the available data.

Referring next to the endosperm, as is well known, it contains much less of certain of these dietary accessories than the germ, while the concentration is low, the bulk of

the endosperm is, as has already been indicated, relatively large, and consequently as nearly as I can estimate the quantity of B_1 contained in the endosperm is as great as that contained in the germ, roughly one-sixth to one-seventh of the total quantity present.

Now, the sum of these two estimates, and I am referring to B_1 particularly because our data are much more adequate and precise than in the instance of some of the other accessories, the total quantity or the sum of these quantities then becomes roughly one-third of the total and we must thus assume that the remaining two-thirds or thereabouts of the thiamin and possibly although again my evidence is not too clear, of the other dietary accessories, of certain other dietary accessories, such as B_2 are present in the pericarp and testa.

Exactly where they are located in those several
1531 tissues has not yet been determined, to be sure, and is a little difficult to determine. Incidentally, I might refer to hypotheses which were advanced by one of my colleagues in a conference the other day, which should be distinctly labeled as hypotheses but rather interesting at this juncture.

Is it possible that thiamin or Vitamin B_1 plays a role in the synthesis of the carbohydrates as well as in their metabolism? If that be true, we would expect to find the highest concentration of this particular type of accessory in those tissues which are richest in carbohydrates, yet that is not the case.

However, we know that thiamin is freely soluble in water and this is a hypothesis that was advanced:

Suppose that it is true that as concentrations fairly high in these tissues during the time when they are there deposited there by the mother plant, we know that in the final stages of maturity water moves outward from these rather moist tissues, to the atmosphere, as the grain finally matures and ripens.

May it be that the thiamin moves in water solution, from the center to the outside and then as the water vaporizes into the atmosphere, the thiamin remains deposited in those last tissues which it reaches?

Now, I recognize full well that there are several
1532 flaws in this hypothesis but it is an interesting one at least, and may serve as a basis for later investigation if that proves feasible.

Now, I have discussed the wheat grain up to this point in large part at least in terms of its relation to the life of the wheat plant.

After all, this wheat grain is not produced for feeding man. The mother plant is not concerned with our nutrition or metabolism at all. It is concerned only with continuing itself as a biological species, and these structures, accordingly, and their composition, are determined entirely by the plant in terms of its requirements.

We come along then, and as I have remarked on a former occasion, paracentesis the wheat plant by trying to take something from it that it does not really produce for our use, or needs, and in so doing we try to make the best of the somewhat unfortunate situation with which it leaves us, in that connection, unfortunate to the extent that we may discern useful materials in the structures which are faulty from other points of view or which contain useless materials from other points of view, notably that of our own needs.

Now, I suspect an ideal of flour milling would be to mechanically separate or fractionate the wheat grain into these component structures, these three groups of
1533 structures that I have just outlined, but unfortunately the mechanical and other facilities of the present-day flour mill are not entirely adequate to that end.

To begin with, the miller does take off bran and shorts, but if you examine those materials carefully you will find that they are fairly rich in crushed and disintegrated cells of the starchy endosperm. The bran and shorts contain considerable amounts of flour, in other words, derived from this central tissue.

The bran containing the less commercial shorts contain perhaps twice as much in many instances as the bran.

In the instance of the germ or embryo the situation is perhaps still more unfortunate to the extent that even despite its relatively small volume in percentage in the grain we don't recover in milling a very substantial fraction of even that small amount. As nearly as I can discern from scrutinizing the records and the products of various mills, they are doing fairly well, even where they get the germ out at this time, to recover 10 per cent or thereabouts to recover that amount in the mill at any one time. It is conceivable that future developments in the art and technology of milling may improve that situation and enable the miller to recover more.

Presiding Officer Willcox: Does that mean that the rest of the germ adheres to the bran as it is separated,
1534 or that it is mixed partly with the endosperm?

The Witness: The rest of the germ becomes flaked in the process of reducing certain middling streams and bolts out with the coarser products that ultimately appear in the shorts, and the shorts are fairly rich in that particular tissue.

Presiding Officer Willcox: The separation from the endosperm is fairly complete?

The Witness: It separates, and the separation from the endosperm in the instance of the recovery of the high grade flour is quite complete, and those flours will contain only traces, occasional fragments of the germ tissue.

As we go down through the process of milling, and approach what are sometimes called tailing streams, then you will undoubtedly find the proportion of germ structures to be increasing substantially, especially the flours which are milled from what I call secondary middling, by regrinding the middling streams.

Now, it is obvious in view of what has already been said about the recovery of these two structures, that one does not recover all of the endosperm in the instance of the flours, because part of it has already gone with the bran and shorts. I don't doubt that members of this committee and others concerned are already familiar from this hearing, and from their own knowledge of the general
1535 processes in flour milling, and unless it is desired that I do so I won't refer to them in further detail, except to emphasize at this point that the mechanical facilities now available permit of the recovery of only part of the endosperm as flour, and in the average mill, the typical roller mill, it is fairly safe to assume that when they are milling high grade wheat, wheat which is normally plump and well-filled, that the recovery of what is ordinarily regarded as the total edible flour, that is the flour characterized in the trade as straight grade, there will be in the range of 72 to 75 per cent of the total weight of the grain. These percentages in all cases are corrected to the same moisture level, to be sure.

Now, in addition to this straight grade flour there appears at various stages in the milling process certain streams which are frequently recovered and sold as so-

called low-grade or Red Dog flour, and if they be superimposed then upon the straight grade flour that will bring the total recovery of the boltable material up into the range of 74 to 78 per cent, or thereabouts. I believe it is safe to take as a working level, in this instance, 76 to 77 per cent, by weight of the grain.

To extend the recovery of boltable material beyond these limits will necessitate a re-treatment of certain of the offals or by-products of milling, notably, for example, 1536 of the shorts.

In other words, to get into higher levels of extraction than those I have indicated it would be necessary for the milling process to be revamped somewhat, no doubt, in order to recover boltable material, that is, material which will pass through a flour sieve, and that only in the event of a more extended treatment.

Now, with that as a basis for the next phase of the discussion, I wish to direct your attention to the chart at your left. In this particular chart, the solid black line that I am indicating with my pencil—

Mr. Goodrich: If we can get that into the record now; I believe it would show up better.

Mr. Campbell: I would like to offer in evidence, Millers National Federation Exhibit "Q". This is entitled "Vitamins B_1 and B_2 as Related to Per Cent Extraction," and I think that you have a line there for iron, too?

The Witness: That should be revised to include "and Iron."

Mr. Campbell: The thing balck line on this one is the iron?

The Witness: Yes, marked "F-E."

Mr. Campbell: The thin black line is the B_1 line and the heavy black line is the iron.

Presiding Officer Willcox: The heavy black line 1537 is the one appearing in red on the chart.

The Witness: Yes.

Presiding Officer Willcox: Is there any obection to the admission of this Exhibit "Q"?

(No response.)

If not, it will be received in evidence and so marked.

(The document above referred to was received in evidence and marked MILLERS NATIONAL FEDERATION EXHIBIT "Q.")

The Witness: If there is no objection, I will insure that the black line is labeled "iron." It should be on there but

through an oversight that was omitted, so we will mark it "FE" if you please, the symbol for iron.

Now, referring to the large copy of this chart here on the stand, this solid black line is intended to represent the levels of B_1 or thiamin content of flours representing in turn different percentages of extraction, by 5 per cent intervals beginning at 60, and ranging through to 85 per cent; the broken line of equivalent data for B-2, in terms of micrograms per gram. The B_1 I should have indicated is in terms of international units per gram, and the red line here depicts the equivalent data for the iron content in per cent, with the values indicated along here, in terms of one thousandth, and two thousandths, and three thousandths per cent.

1538 In the instance of the curve representing the appearance of thiamin or B_1 in flour as a function of extraction, it is obvious that there is a steady but small increase in processing from a 60 per cent extraction which would represent a relatively short patent flour, to 70 per cent extraction which would approach the equivalent of a straight grade or long patent flour, but that when we pass the 70 per cent extraction mark, the relative as well as the absolute increase in the thiamin content is markedly accelerated, and reaches its highest rate of increase in the interval between about 73 per cent extraction and about 78 per cent extraction.

Incidentally, that is the range through which the patent flours are accumulating, patent or straight grade flours are accumulating these tailings flours, so-called low grades and Red Dogs, and the like, as the latter are superimposed upon the more highly refined flours.

In the instance of B_1 as we pass the 78 to 80 per cent extraction level, the further rate of increase in the B_1 content is decelerated, or slows down, although it does continue until we reach the level of whole wheat at 100 per cent extraction.

Now, it is essential to emphasize separate features of the data represented by these curves. In the first place,

1539 I suspect that these values are higher than the average for the equivalent extraction of flours through the mills of the United States as a whole because such data as have come to light seem to indicate that the hard wheats from which these flours are milled tend to run a little higher in their thiamin, possibly also in their ribo-

flavin content than do the softer wheats of the eastern certain western western States but again our data are not adequate at this juncture to enable us to get up either averages or ranges for these different types of wheat, and of the flours milled from them.

Also, I should emphasize that there is a substantial error attached to the determination of thiamin content of such materials, and an even larger error attached to the estimates of the riboflavon or B_2 content, so that in both of these instances these curves would doubtless be best expressed by broad bands rather than sharp lines, and should be so interpreted.

Now, the significance of these data, and the general facts concerning milling in the present instance, to my mind at least, and to this committee, might be stated somewhat as follows:

If this committee desires to recognize the nutritional characteristics of a long extraction flour, it might give consideration in the public interest—

Mr. Campbell: When you speak of "committee" 1540 you mean "Administration?"

The Witness: Exactly, yes, I am sorry. To the Administration.

It might give consideration in the public interest to a standard for such flours which would admit the naturally milled flours of 76 to 77 per cent extraction, which would involve setting a minimum thiamin content in the range of six tenths international units per gram, to one international unit per gram. That is in this range here, in this chart.

That is equivalent, according to my calculations to 207 to 450 units per pound or .825 to 1.375 miligrams per pound.

In the instance of riboflavin, at .75 to 1 microgram per gram.

This would avoid much of the added costs of reinforcement with synthetic vitamins of vitamin concentrates. The cost of adding to such material of say 10 milligrams of nicotinic acid would probably be less heavy than substantial riboflavin and/or thiamin reinforcement. If a ceiling or maximum level must be included in the standard, it should be high enough to admit any natural long extraction flour that would be encountered. This would also permit of reinforcement of shorter extraction flours, with syn-

thetic vitamins, should experience or popular demand dictate that practice.

1541 As nearly as I can deduce from the available data this would involve the setting of the maximum at about three times the suggested minimum.

If consistent with the policies under the present Act, and of this Administration, it might be appropriate to so phrase the definition as to admit any natural wheat flour to this category, to which no synthetic vitamin or Vitamin concentrate had been added. In other words, if future progress in milling technology should result in making flour streams available which if included in the finished flour would elevate the concentration of these accessory substances above the levels indicated, such flour should be admitted to labeling and sale under whatever classification is set up here to characterize these high vitamin flours.

Interpolating a comment at this point I feel that we can't anticipate wholly at this time, what advances in milling technology will make available certain of these deposits of thiamin which we have every reason to believe are in these outer layers, so that they may be recovered and diverted to flour without detracting from the quality and general appearance of the latter, and for the information of this group, in this connection, I have here at the head of the table a series of loaves of bread, baked from a standard patent, a 60 per cent extraction which is es-

1542 sentially analogous, and a 70 per cent extraction, and 75 per cent extraction and 80 per cent extraction, that is, with the corresponding flour samples from which these loaves of bread have been baked, that is 60, 70, 75 and 80 per cent extraction, which will accordingly have the approximate thiamin and riboflavin concentrates indicated here.

Mr. Campbell: Before you proceed on that subject, it would be impracticable to offer this bread and these samples of flours in evidence, and I think that it would be instructive to just make some comment about the distinctive or differences between the different kinds of bread and flours.

The Witness: Yes. The bread made from the 60 per cent extraction flour is quite typical of pan bread sold in the American stores today. That is of superir texture as that is ordinarily rated in baking technology, of rather light, pleasing white color.

As we extend the extraction, as is usual in such instances, the shade of color departs from the whiter color of the shorter extractions, each being successively somewhat darker in hue. The most noticeable difference, to be sure, is found between the 75 per cent extraction loaf, and the 80 per cent extraction loaf, which is distinctly darker in color, and has a somewhat different and more dense crumb.

I would also like to emphasize at this juncture the fact
that recent wheat crops in the Northwest, in fact
1543 in the Great Plains area generally, have been unusually high in their gluten content and baking strength, and these flours here represented and the bread baked from them are possessed undoubtedly of higher level of so-called baking strength, meaning by that the facility with which it can be converted into high quality bread, than is true in the instance of what we used to regard as normal and actually lower gluten flours and breads.

If it should chance that in the passing years the precipitation in the Great Plains area should return to what we regard as normal, and the gluten content recede as would almost be inevitable in that instance, the general baking behavior of these long extraction flours would perhaps not be as acceptable to the baker from a technological standpoint as in the instance of the flours of the 1940 crop, and the crops which have immediately preceded.

I would also like to refer briefly to some of the technological problems involved in handling these longer extraction flours. As these loaves, baked by an expert technician, to be sure, pass before us, they look quite acceptable but that does not always reflect the griefs and difficulties encountered by those same technicians in making the conversion from flour into bread.

Specifically, as we superimpose these streams which
appear at the tail of the milling process, in extending
1544 our extraction in such a range as this, for example,
we carry into the flour and hence into the bread dough certain enzymes which may be more or less devastating in their action, and which seriously complicate and render difficult the fermentation of the dough, and especially its handling through the more or less complicated mechanical devices used in modern bake shops, in dividing and rounding and molding the loaves before baking.

Now, a few moments ago I referred to the matter of costs, in keeping the recovery of useful nutrients down

as low as possible. Thiamin and riboflavin in pure forms or as concentrates are still rather expensive materials, and any substantial addition to flour of either or both must perforce increase the price of the finished flour.

Again there is the matter of the cost of assays or analyses in controlling manufacture and policing the sales. Very few milling organizations or laboratories are now provided with facilities adequate to the control of commercial production insofar as Vitamin assays are concerned. Equipment for these purposes is both expensive and intricate. The average flour mill control chemist is not familiar with the techniques nor competent to immediately assume responsibility for accurate assays. Somehow these costs of having the assays made in an outside laboratory, or of training personnel and pur-
1545 chasing equipment, and carrying out the hour by hour tests, must be met. The higher the minimum level, the more precise the requirements for tests, and the narrower the tolerances, the more expensive does this control procedure become.

Also, there may be a greater hesitancy on the part of the moderate sized and smaller units in the milling industries to actively embark upon a program of production of such flours as are under discussion. In the case of nicotinic acid levels, it may be necessary at the outset to set the standards in terms of actual additions, rather than the total quantity present, since we lack information at the moment as to the concentration in natural flours at different levels of extraction, and do not have adequate methods available as yet for assaying the natural flour, or the finished product.

On extending the degree of extraction of flour above the hitherto customary levels of patents, straights, and clears, the mineral content of the resulting flour is also increased considerably. This is made evident most easily from the ash content.

The concentration of ash in the wheat grain reaches its highest level in the bran coverings and in the germ. Now, the protein content of flour is increased also on extending the extration, but not to anything like the same degree. It appears to be a convenient work-
1546 ing factor to assume that if the ash content of flour is increased by 100 per cent, as for example from .40 per cent which would be that of a fairly short patent flour, to .8 per cent, which would be about the

average ash content of a hard wheat .80 per cent,—78 to 80 per cent extraction, the protein content will be increased by about 10 per cent, as for example from 12.5 to 13.75 per cent, in the instance of this series of data.

This means accordingly that the mathematical formula which I understand has been proposed for inclusion in the standard for flour, namely, that the limit of ash shall be the protein content divided by 20, plus a constant .30, may need revision to adapt itself to these flours of extended extraction. I feel that the constant .3 might conservatively be increased to at least .5, if the Administration determines to include ash limits or specifications in the standards for flour which will admit and encourage the production of these long extraction but higher vitamin flours. The average ash content of a series of wheats which we examined recently in my laboratory, was 1.70 per cent, on a 13.5 per cent moisture basis. Incidentally, may I indicate that we have completed detailed analyses of some forty-four samples of typical hard spring wheats of known varieties, grown through the hard spring wheat area, determining the copper, iron, calcium, and magnesium as well as the total ash content of each sample separately, and if those data are of any interest or value in this connection I will be glad to file them in that case. I don't feel that it is advisable necessarily to read them into the record at this juncture unless they will be singularly useful in some further connection but I believe that we have a rather good picture, chemically speaking, of the concentration of those particular elements in our northwest spring wheat, and the data are otherwise unpublished, or I would cite them.

1547

Referring to this matter of ash content in another connection, I sketched on a chart the apparent relationship between the ash, and the thiamin or B_1 content in the instance of one mill's output of flours of increasing extraction, and in that particular series the relationship between those two constants appeared to be essentially linear, that is, a fairly straight line, but I can not represent, because of lack of data, that they are typical or average, but using them in their present form it appears that the mathematical expression, ash in per cent, minus four-tenths, over the B_1 content in international units per gram, minus one-tenth, equals a constant, 2.667, so that by the application of that particular mathematical formula, one can derive one value from the other.

Mr. Goodrich: Will you restate that formula,
1548 please, sir?

The Witness: I will be glad to leave it with the reporter, if you like. Here it is for your convenience.

(The formula referred to is as follows:)

$$\frac{\text{Ash in percent—0.4}}{\text{B, in I. Units per gram—0.1}} = 2.667$$

The Witness: Now, let me emphasize in this connection that that particular factor may apply only to this one series of data, and it will require further research, or further analyses to ascertain its general applicability, in fact my principal purpose in mentioning it at this time is to challenge as it were, those who have such data, or access to them, to make a comparison with this finding, to determine how generally it may apply.

Also, I wish to stress the fact that that equation, as thus expressed, applies only to a series of flours representing a progressive increase in the percentage of extraction. I am satisfied that it will not fit a similar comparison of the ash content and thiamin content of flour mill streams, in any individual mill, or as between mills, because there we find sharp irregularities, at times, in the relationship between ash and thiamin content.

It is also desirable to stress at this juncture the fact that when the extraction of flour is extended beyond the equivalent of a straight grade, that is, down in this
1549 range of 72 to 74 or 75 per cent, the number of bran specks will increase, as you superimpose these tailings flours upon the straight grade, and all of these may not pass through a 100 mesh screen. This will be emphasized if the total extraction exceeds 75 per cent, and recourse is had to regrinding shorts to increase the flour yield.

It is curious, but true, that a flour product which has all been bolted through a fine sieve of a given size may not go through the same sieve later when rebolted. Accordingly, it will be necessary to alter the proposed specifications for flour insofar as sieving tests are concerned, if the flour specifications for this particular situation are to be open to include the products resulting from an extended extraction above the level of 76 to 77 per cent.

I should also stress the fact that in the instance of increasing extraction, with the consequent increase in ash content and thiamin content to which we have already

referred, that the data now available seem to indicate that the variability, both proportionately and in terms of actual concentration, will increase, as we rise from the lower ash, shorter extraction flours, to the longer extraction flours. What the boundaries of the limits of this range may be, can only be determined as our data are increased in volume, but I am confident, from the facts
1550 at hand, that we will encounter that diverging limit of analysis, that it will spread out more or less fanwise. That is, as we advance into the higher levels of thiamin content we may expect the variability and the range to become greater, whether we express it in terms of extraction or ash content or any other scheme or system which we set up to characterize these flours resulting from the extension of the milling process.

This large variability can be expected to appear in the returns of the laboratory in consequence of the single or joint operation of at least three sets of factors, namely, one, the relatively large experimental error of the analytical or assay determinations in the first instance. That is, the data as set down in the laboratory book by the analyst:

Second, the variability among the wheats used in milling, as a function of both varietal differences, and the effect of the environment in which the wheats are grown.

May I say that there are surveys now in progress which should during the course of the year enormously, relatively speaking, expand our knowledge of the significance of these variations, but even with the limited data at hand it is quite clear that the variability is going to be large, and;

Third, the variations in milling processes as between different mills, and even in the same mill, particularly
1551 when new practices are introduced in an effort to extend the extraction.

Finally, reference might properly be made to some of the more prominent technological problems involved in converting long extraction flours into bread. I have already referred to that casually, in discussing certain characteristics of these loaves before us. One can not properly dismiss with a wave of the hand the assumption that these long extraction flours above 75 per cent or in that range, can be baked into bread for example with the same ease and the same results as in the instance of the patent flours with which the housewife and bakers are now familiar.

and for which the technological processes of the modern bakery have been developed.

These extended extraction flours yield doughs of different physical properties, from those to which we have hitherto been accustomed. They contain more active enzyme combinations, including proteases, that degrade the gluten and render the dough sticky. These combine to render the conversion process much more tricky, and difficult of control. The bakers should not be deprived of access to stabilizing agents, otherwise innocuous and harmless, which facilitate the control of conversion processes. Specifically, certain bleaching and improving agents may be of more service here, relatively speaking, than at present with white flour. Moreover, I do
1552 not know of any evidence that definitely demonstrates any harmful effects of these conventional reagents with which the milling and baking industry have long been familiar, and such as have been under consideration, I believe, in connection with the flour and bread standards, since the suggestion has appeared occasionally in the literature, and in open discussion, that bleaching agents inactivates or destroys Vitamin B or beta-carotene, may I emphasize that the work in my own laboratory and more recently in the publications of Zechmeister, have shown that the carotenoids, of the flour, are largely or in fact almost wholly, of the xanthophyll type that do not constitute a provitamin B.

These, then, are certain of the considerations which to my mind merit careful consideration and analysis, in arriving at a rational and feasible program of recovering the natural vitamins of wheat, and communicating it to the consuming public, in the form of acceptable breads.

Mr. Campbell: Doctor, I think that it would be helpful if you could just state briefly or give some description of this milling process, not to any great extent but the separation of the streams, and the practical problems of that kind.

The Witness: The major departments in the modern rolling mill might be described essentially as follows:
1553 First, the break system, which has as its primary function the separation of the more fibrous bran and shorts from the endosperm particles that appear in that process, with the production of as little flour as possible.

From the break system then we recover characteristically three major types of products: The bran, the granular

middlings, and the break flours. Each of these is to all intents and purposes—I beg your pardon, the first and third are to all intents and purposes, finished products except that they may be blended or combined with other streams later in the process.

Now, directing your attention to the granular middlings which appear at this stage, they are coarse, more or less cubical fragments, comprised largely of endosperm material, but often having adherent to them portions of the adjacent pericarp, to be sure, and in certain instances mixed with the still intact germ or embryo.

These streams as they come away from the break system are passed through what is known as the purifiers, where a further classification is effected largely on the basis of size, in order to recover for the next stage of the process, streams or materials which are reasonably uniform in their physical characteristics.

Then these classified middlings, as they emerge from the purifier system, are conveyed to the reduction rolls
1554 which are heavy cylindrical steel rollers, running at a slight differential, where they are ground into flour and certain materials which do not have the fineness of flour and which are recovered when the flour is bolted out. The flour thus recovered is known as middlings flour and usually bears a number, to characterize the head miller's idea of the nature of the middlings undergoing reduction, so we have 1, 2, 3 and so forth, middling streams.

When these ground middlings are bolted, and the flour removed, certain materials remain which are not of the fineness of flour, and which for convenience I commonly refer to as secondary middlings—that is, they are particles which have been partially ground in the initial grinding process, and from which further, or more flour can be obtained on re-grinding.

The secondary middlings are then conveyed to another set of rolls, where this reduction process is continued. Only when the flour from this second reduction or reduction of the secondary middlings, is bolted, we find that it contains more particles of pericarp, and also in certain instances of germ as well, than did the choice middlings flour resulting from the initial grinding of the primary middlings.

Now, in bolting off the secondary middlings flour some material remains, which from the physical and chemi-
1555 cal examination obviously still contains some flour and so they may be reground and then we begin to

recover the tailings flours which appear in these later stages of milling, which are darker in hue, which tend to possess some of these less fortunate biochemical characteristics from the standpoint of the ease of conversion into satisfactory bread but are high, to be sure, in their thiamin and riboflavin content. As they are removed and superimposed upon these streams that have appeared before, those characteristics are built up as suggested by this curve.

As this committee, or this group, is doubtless well aware, in the conventional technique for characterizing these flours, in this progression of events in the mill, is through the medium of the ash determination, the latter mounting rather steadily as we progress from these highly refined middling flours, through to the tailings flours that appear toward the conclusion of the process.

Now, there are also certain special types of flour streams that appear particularly in the larger, and more extended milling systems, so-called duster flours, which represent low-grade material, as judged by the bakers' and millers' point of view, and which result from the special mechanical treatment of bran and shorts, which commonly find their way into the low grade and Red Dog, designed for
1556 animal feeding, but still having essentially the fineness of flour to the extent that they can be bolted through some of the coarser flour sieves.

Now, as this reduction of the secondary middlings ensues, one recovers at certain stages of the process, small bran fragments mixed with more or less flour, which is bolted off and constitutes in each instance a portion of the potential shorts recovery. That is, several of these streams when spouted together at the appropriate time, would make up the mixture which is commonly known in the milling industry as shorts or sometimes as middlings. That is, the term "middlings" as used in the latter connection is entirely different from the application to these granular flour middlings to which I referred earlier in the description of the process.

Now, those are the major phases of flour milling. There are all sorts of variations upon this general theme, that are run by individual mills, according to their mechanical equipment, and the ideas and sometimes the whims and prejudices of the superintendent miller.

Mr. Campbell: Now, Mr. Bailey, will you please develop the practical implications of retaining or adding back the

germ to increase the nutritive properties of flour, and the effect the germ has on doughing and baking qualities?

The Witness: I have here a series of flour samples, representing standard patent alone and mixed with 2½, 5 and 15 per cent of germ respectively, and here are the
1557 corresponding loaves of bread made from these four samples of flour. The 2½ per cent of germ was selected, because that is approximately the equivalent of the proportion of germ in the entire-wheat kernel; 5 per cent is to be sure, double the first figure; and 15 per cent was included because the bio-assays and analyses have shown that it requires approximately 15 per cent of germ or sometimes even more, depending upon the relative purity of the commercial germ available, to bring the thiamin content of the resulting mixture, with patent flour, to about the level of that of whole wheat from which the flour and the germ respectively were recovered.

Now, the loaves of bread tell a more graphic story than my description can be. Suffice it to say for the purposes of the record, that this particular lot of flour stood the effect of the additional 2½ per cent germ, represented here, fairly well. It is just a shade darker in color, to be sure, and yet the general texture, the crumb qualities, and volume, and other physical characteristics by which bread is ordinarily appraised, are sufficiently similar to that of the untreated loaf to enable one to say that it is approaching or close to the normal in that particular, at least it has not been sharply degraded.

The effect of the 5 per cent germ are fairly consider-
able, not all of them being registered in terms of
1558 the appearance of the finished loaf, because here again, as I mentioned in the instance of these longer extraction flours, the situation is complicated in the bake-shop by a tendency toward a greater stickiness, and consequently mechanical difficulties in handling the dough through the various machines, and otherwise.

The addition of the 15 per cent of germ is, as you can see, very unfortunate indeed. The loaf would not be regarded as a normal, saleable loaf in any sense, and the baker who handled it was in grief right from the outset, in keeping himself detached from and not enveloped in the dough which he was endeavoring to handle.

Mr. Campbell: How about the size of it, for the record, as compared with the other samples of bread?

The Witness: Just making a rough estimate, the difference in volume, I would say it is less than 40 per cent of the normal or untreated loaf in terms of volume displacement.

Mr. Campbell: And very considerably darker?

The Witness: Very much darker, and with all of the undesirable crumb characteristics which the baking technologist would associate with that, and anticipate from that decrease of volume.

Presiding Officer Willcox. Are all of those loaves of the same weight?

The Witness: They are all made from the same
1559 weight of flour, initially.

Now, the conclusion that I presume that may be reached from all of this, is that the addition of wheat germ as such does not afford a very feasible medium for elevating the thiamin and vitamin nutritional quality of bread, at least to anything like the level that can be achieved by other practices.

I should also emphasize that as indicated in my earlier presentation, the recovery of germ from wheat is in no sense complete. If we attempted to set our goal at 2½ per cent of added germ, it would take about all of the germ that the average mill could recover from ten bushels of wheat to reinforce the flour to that level that was produced from one bushel of wheat, and then we would still be away short of the thiamin content, at least, and doubtless the other nutritional accessories as well of that present in the whole wheat itself.

By Mr. Campbell:

Q. How many bushels would it take on that 15 per cent?

A. Now, just engaging in a little mental arithmetic, if my ratio of 10 to 1 was correct on 2½ per cent, we have six times as much here, so that would bring the ratio to 60 bushels of wheat to produce enough germ to reinforce the flour mill from one bushel of wheat on that level.

Q. Now, could you state, Doctor, the B_1 content of
1560 these various samples of bread that you have been speaking about, with the germ added?

A. I have those data, if I may refer to my notes. This particular short patent flour contained in the range of .2 International Units of Thiamin, or B_1 per gram, or two-tenths.

Mr. Campbell: I would like to introduce in evidence, Millers National Federation Exhibit No. "R", a chart that

has the legend on it "Effect of Added Wheat Germ on Vitamin Content of Flour."

The Witness: In the instance of this chart, the solid line represents the levels of Vitamin B_1, the broken line represents the levels of B_2 or riboflavin as nearly as the latter can be determined.

In the instance of thiamin, the particular flour here used contained in the range of .2 International Units of thiamin per gram, untreated. Two and a half per cent of germ elevated that to about .4. Five per cent to about .6, and 15 per cent to a little more than 1.4 International Units per gram. And the latter is probably a rather low level for spring wheat.

By Mr. Campbell:

Q. Can you relate that to this sample of 15 per cent germ, of the bread there?

A. The point indicated here, the 15 per cent level, 1561 and containing 1.4 plus International Units per gram, when converted into bread had the results shown in the instance of this loaf, which is extremely dense, dark in hue, and so on.

Q. And about 40 per cent of the size?

A. I should say a shade under 40 per cent of the size of the volume of the normal or untreated loaf.

Q. How about that riboflavin, do you want to talk about that?

A. The riboflavin content will perforce increase likewise. If the germ contains the high concentration we assume, in the instance of these assays, the estimate is about 5 per cent of that, or rather five-tenths of a microgram of riboflavin per gram of flour; in the untreated or short extraction flour, a little less than .7 when 2½ per cent of germ is added, and approximately .9 with 5 per cent of germ, and about 1.6 International Units, or 1.6 micrograms per gram when 15 per cent of germ is added, which again as in the instance of B_1 concentration is probably that of a low vitamin wheat.

Presiding Officer Willcox: Is there any objection to the introduction in evidence of this chart? If not, it will be marked Millers National Federation Exhibit "R".

(The document above referred to was marked MILLERS NATIONAL FEDERATION EXHIBIT R and received in evidence.)

1562 Mr. Campbell: I think that that is all.

Presiding Officer Willcox: We will recess for about ten minutes.

(Recess.)

Presiding Officer Willcox: We will proceed, gentlemen.

By Mr. Campbell:

Q. Dr. Bailey, I believe that you told me during the recess that there was something that you were not sure whether you had put in that you would like to explain in connection with your testimony.

A. I thought that it would be well to emphasize before we left this phase of the subject that the data expressed in these graphs or charts and in my statements are not designed to be represented as averages, or as limits. It should be emphasized that the particular data that were in that first chart, I believe designated as Exhibit "Q" were derived from the study in one mill of one type of wheat, which after all represents a relatively small percentage of the total wheat being ground in the United States today.

Q. What type of wheat was that?

A. That was milled from hard spring wheat, or a mixture in which hard spring wheats predominate.

Q. Do you know about what percentage that would 1563 be, or would represent of the total wheat production?

A. Well, in the instance of the 1940 crop, my guess would be somewhere around a fourth to a fifth, but that is just an estimate on my part, I don't have all of the wheat statistics at hand, but at any rate it is presumed to be a reasonable representative of that type of wheat in that one mill.

However, there are other market classes, or types of wheat which are being milled in other sections of the country, which may or may not measure up to these specific standards. As a matter of fact there are some indications that some of them will not reach the levels indicated here, and while I believe that that was mentioned in my earlier statement, I felt it merited emphasis to avoid the implication that these were designed to be typical or average.

Presiding Officer Willcox: Is that all that you have?

Mr. Campbell: Yes, that is all.

Mr. Goodrich: If anyone cares to go ahead, they may do so.

Presiding Officer Willcox: Are there any questions?

Dr. Lee: I would like to ask for a repetition of that formula that was given, and this can be off the record, 1564 for that matter.

(Whereupon, the then following discussion, by the direction of the Presiding Officer, was not placed on the record.)

Presiding Officer Willcox: You may proceed.

Cross-Examination by Mr. Goodrich.

Q. Doctor, all of your testimony has related to the hard wheat primarily used for bread-making?

A. That is correct.

Q. And none of it so far as you know is applicable to the soft wheat used for that purpose?

A. No, I have seen relatively few data relating specifically to authentic samples of soft wheat.

Q. Is your data confined exclusively to the hard spring wheats?

A. Yes, essentially so, or mixtures in which they predominate.

Q. Is it possible to obtain a 76 to 77 per cent extraction from any wheat other than this hard spring wheat, so far as you know?

A. Yes, I think that you could obtain it from any normal plump heavy hard wheat, such for example as better grades of hard winter wheat. I don't think that there would be any difficulty in reaching the same levels of 1565 extraction, certainly not from thin, low-test weight hard wheats of any class, however.

Q. You could not reach it from those?

A. No. Your extraction would be progressively reduced as the wheat per bushel comes down on the average.

Q. And your extraction, the percentage extraction would be reduced as you started using the soft wheat, would it not?

A. As a general trend in the direction of greater difficulty of separating the flour from the bran and shorts in the instance of soft wheats, except in the instance of a limited number of mills that provide unusually long extraction systems, as applied to the soft wheats.

Q. Do you consider the practicability to establish a standard of identity on the basis of the percentage of ex-

traction from the wheat berry—do you consider it practicable to do that?

A. Now, let me see if I understand the import of your question correctly. We are not referring to nutritional properties, or anything of that sort, but merely to the issue of defining flours in terms of their percentage extraction.

Q. Assume that the nutritional point will be taken care of at a later stage in this hearing, I am now directing your attention to the practical milling questions, whether
1566 or not it would be practicable to establish a definition and standard of identity on the basis of the per cent of extraction.

A. Only very approximately, sir, in the instance of all types of wheats in all types of mills.

Q. Different types of wheat milled to the same percent extraction would vary rather greatly in their makeup, would they not?

A. Oh, yes, both chemical and physical.

Q. What limits of extraction can be attained without regrinding and reworking the bran, and the middlings, and so forth, through a regrind and bolting them back in?

A. As I indicated in my introductory statement, and again I am limiting the thing sharply to the better grades, the upper grades of hard spring wheat, in the range of 76 to 77 per cent.

Q. How was this 80 per cent extraction flour used in the preparation of one of the loaves of bread, exhibited with the sample, obtained?

A. That degree of extraction has to be produced by manipulation of some of the shorts to recover it, in addition three or four per cent of the material is superimposed upon the materials produced by normal extraction processes, and our only reason for running it up into that range was to have a progress by 5 per cent units.

1567 Q. Would it by re-working be practicable to obtain an 85 per cent extraction?

A. By re-working you can obtain any extraction that you choose, from one to 100 per cent.

Q. You can do that?

A. Well, if you resort to sufficiently heavy and vigorous regrinding of these fiberous materials, but it would be an intricate and difficult job, as you approach the more fiberous extremes.

Q. Even the 76 to 77 per cent extraction flours will not pass the 100 mesh woven wire screen, you say?

A. I wouldn't expect them to do so, on an ordinary standardized sieving, because you are likely to pick up from those tailing extremes more or less fiberous particles which happen to be tilted just right so that they went through the sieve on the original bolting, but may find themselves in another plane at the time that they hit the test sievers.

Q. What type of wire will they go through, what type of sieve, if they will not go through the 100?

A. I can only guess now.

Q. You have no sieving experiments with that?

A. No, this is a new experience confronting us now, when we get up into these higher levels of extraction, and it would have to be appreciably coarser than the 1568 sieves on which you try to bolt off your material in the mill initially.

Q. As the coarseness increased, the baking qualities would be affected, would they not?

A. Now, when we speak of coarseness, we are agreed that we are referring primarily to increased fiber and ash content, and the answer to that is "yes."

Q. You consider some specified degree of fineness, an essential characteristic of identity of these long extraction flours?

A. You mean could I sit down and write specifications that would fit unit percentage extraction?

Q. Do you consider that necessary in order to establish the identity of the flour?

A. Well, I am too unfamiliar, I am afraid, with the intended practices under the new law to conform to the requirements, rigid requirements of your question. I would have to study that a bit before I would know just how to reply. I assume that it would be desirable to write specifications for flour or standards of identity as you call them that would admit such flours as are here represented in these instances of these longer extractions, certain of these longer extractions.

Q. Assuming that were the desired objective, you would not call a product a flour, if it passed, say, a 20 mesh 1569 sieve, and would not pass a 100, somewhere in between there, it would have to be more nearly to the 100 mesh sieve, would it not, in order to be properly styled and identified as a flour?

A. Either that, or to use a 100 mesh sieve if you pre-

fer, and then admit of a non-passage of a certain percentage.

Q. Can you suggest what tolerance for non-passage would be proper, in this instance?

A. Just as a guess, I would say ten or fifteen per cent.

Q. You have no sieving experience with that to demonstrate that?

A. No, I have not.

Q. In the long extraction flours it is the red dog, and the particles of bran coat along with the enzymatic action which militates against proper handling in the baking, is that true?

A. Would you read that question, I didn't get it exactly.

(Whereupon, the pending question was then read by the reporter, as above recorded.)

The Witness: Yes, essentially so, it is the tissues or the materials that are characteristic of the extremes that you
mentioned, which bring these enzymes and the like
1570 into the dough.

Q. It does require some special skill to handle this long extraction flour, in the preparation of the bread?

A. Yes, and particularly so when you get into some of these critical ranges that I mentioned, where you are superimposing these low grade extremes on the straight grade flour.

Q. What with respect to a 76 and 77 per cent extraction?

A. To the extent that that involves the addition of these low grade extremes, it becomes increasingly complicated.

Q. It can be obtained without unreasonable amount of superimposition of these red dog and bran extremes?

A. Well, when we talk solely in terms and strictly in terms of percentage extraction, then we must of course immediately qualify our reasoning, and statement on the basis of the original properties of the wheat. To illustrate, if we chance to have an exceedingly heavy plump high test rate wheat we might mix 60 per cent of straight flour, without superimposing any low grade or red dog thereon, and then we would have a higher percentage of the total extraction to be sure, but we would not have the nutritive
virtues that would be obtained by the subsequent
1571 addition of those low grade streams.

Q. And the percentage extraction would not neces-

sarily assure you the same qualities in number of different types of wheat, with the same extraction?

A. I am confident it would not.

Presiding Officer Willcox: When you say percentage extraction, do you mean percentage of the full weight of the whole wheat berry?

The Witness: I am glad that you raised that, because I should have defined that term before. I do. All of these values given as percentage of extraction, refer to the weight in pounds per 100 pounds of the original clean wheat.

By Mr. Goodrich:

Q. Doctor, do you believe that it is necessary in order to promote honesty and fair dealing in the interest of consumers to establish a definition and standard of identity for a high vitamin flour, obtained by long extraction as a separate product from a short extraction flour?

A. I have the feeling that it would partly defeat the purposes of this desire to enhance the nutritive value of American breads, if one were to have two sets of standards in such instances, to the extent that the American housewife is still going to go in and inquire for flour, 1572 it would be desirable if she could still be sold under the name of flour a product which would have these enhanced properties.

Q. You think it not necessary to inform her of the existence of these enhanced flours?

A. Yes, I do.

Q. And you think it not necessary to inform her that the product obtained by milling to get a longer extraction, that that type of flour is being sold her and not a short extraction flour which she has been accustomed to?

A. Yes, I do. I think that the designation should carry some supplementary term or expression that would inform her.

Q. You think that she should be informed?

A. Oh, yes, I think that she should be fully informed, but at the same time I think that it would be unfortunate to sell it to her under some term other than flour, it should be defined as to these properties.

Q. Is it your opinion that this long extraction flour is substantially the same product as flour now produced?

A. No, I think that there are a few flours on the market now, except certain very special types of flours, which

are of the type which we have been chiefly discussing,
1573 that is these extended extraction flours, there have been some appearing, specialities in recent times, but rarely as far as I can discern are they offered as yet in the household trade, at least.

Q. Where they are offered, they are offered now as specialities?

A. Well, I am afraid that my familiarity with that is not sufficient to enable me to say.

Q. Assuming that a 76 to 77 or an 80 per cent extraction flour were offered for sale in the general trade, would the consumer know how to handle it, in the preparation of bread and biscuits?

A. Well, I imagine the average household as well as the commercial baker would have to revise some techniques, and to do some things a little differently than would be the case with a short patent flour, yes.

But I believe that it would be vastly easier to adapt new practices to flours in the range of extraction that you mentioned, than would be true if the extraction was extended sharply above that, by regrinding in between the shorts.

Q. That is above 80 per cent extraction?

A. Above 76 or 77 per cent extraction.

Q. And the re-adaption of processes and methods would be a necessary consequence of the using of the long
1574 extraction flour, as distinguished from the short extraction flour which he is now using. I take it that the 60 per cent extraction is a typical flour now in use?

A. Yes, reasonably so, yes. The answer to your question is "yes".

Q. I think that that is all.

Presiding Officer Willcox: Dr. Bailey, you said that you suggested as a maximum something in the neighborhood of three times the minima that you were suggesting, for these nutritive ingredients?

The Witness: Yes.

Presiding Officer Willcox: Did I understand you to say that that was in the neighborhood of the highest content of the whole wheat?

The Witness: In the neighborhood of the highest content of whole wheat, and also I proposed that in part to clear the way for the sale of flours which might appear in consequence of improved or modified technological prac-

tices in the flour mill, which would return more of the natural vitamin to the flour, should that eventuate.

Presiding Officer Willcox: What puzzled me was that in the lines on your chart, if projected to 100 per cent extraction, would not reach anything like three times the figures that you mentioned.

1575 The Witness: That is true, but again may I indicate that we have already examined wheats, for example, that have a higher thiamin content than the particular specimen that was represented in that chart, on the one hand, and we don't know how high that level will mount, as our surveys are extended, plus the fact, as I just mentioned, that it would be regretable if we set our maximum so low that we could not admit to the standard otherwise legitimate and desirable products of milling which carried a higher level of thiamin than we can locate at the moment.

Presiding Officer Willcox: Are there any other questions of Dr. Bailey?

Cross-Examination by Mr. Thomas.

Q. Referring to your chart, I think it was Exhibit "Q", you didn't comment on that iron curve there. Wouldn't it be more difficult to retain the maximum of iron by stretching extraction than even the vitamin factors?

A. I neglected to comment particularly on this iron curve, but in this instance the break in the curve, that is the point at which the content of iron sharply increases is farther to the right, that is in a higher level of extraction than the instance of a similar break in the curves of the thiamin and riboflavin content.

1576 However, we note that in this range there is some increase, and at 78 per cent extraction the iron content is approximately double that at the 60 per cent extraction, but still far short of the projection of this curve to the 100 per cent or whole wheat level. Does that answer your question?

Q. Yes. If I read the curve correctly, relatively the iron is deposited in the very outer bran layers, in increasing quantities, even more so than B_1.

A. I agree with that interpretation, it seems to me that there is considerable evidence of that, it seems to be a very worthwhile undertaking to explore that a little further in the light of that assumption.

Cross-Examination by Mr. Hardenbergh.

Q. Doctor, you have been giving some figures which you have gotten from this spring wheat which you have described as a plump wheat, the nutritive values in certain extractions from a plump wheat. Can you say approximately what the extraction would be to get the same results from a 51 or 52 pound wheat such as is grown in the Northwest, in drought years, and rust years?

A. No, I haven't access to any data relating to such wheat. This work got underway, may I say, after we had fortunately emerged from those years, of thin wheat production, and we haven't had access to typical samples
1577 of such material, since these studies were instituted.

Q. But would you say that the extraction, to get the same nutritive results, the percentage of extraction of the entire wheat berry would be very much less?

A. Oh, yes, I am confident of that, that would I think follow as a matter of course, because in the instance of such wheats as you described, the percentage of straight grade flour that can be recovered is substantially lower than in the instance of the wheats depicted by these curves, so that you would start then in terms of extraction from a substantially lower level.

But I wouldn't even dare conjecture as to what would transpire thereafer, if you started superimposing upon the straight grade flour made from a thin wheat, the tailings and low grade streams derived from the milling of the same wheat; we don't know that.

Q. When you talk about a straight grade flour being somewhere around 73 to 75 per cent of the plump wheat, what was your experience as to straight grade extraction on 50 or 51 pound wheat?

A. Well, you are carrying my thinking back several years, but my recollection is that we derived about seven-tenths of a per cent less flour for each decrease in test weight, but I am more or less guessing on that, I would have to consult my records but there is a substantial re-
1578 duction in yield, so if you went down ten pounds in test weight, I would expect that you would get seven or eight per cent less straight grade flour.

Q. That is seven or eight per cent less?

A. That is just an estimate, a quick estimate on my part, I don't recall the exact data.

Cross-Examination by Mr. Thode.

Q. When you answered the question on cross-examination, that your testimony was particularly directed to the study of hard wheat, that did not apply, however, to the general remarks about the milling process, did it?

A. No, the same general types of milling processes are used with all wheats designed for the production of flour, with suitable modifications in detail, as to the exact treatments accorded to be sure on the basis of this relative hardness.

Cross-Examination by Mr. Thomas.

Q. Considering our present milling equipment, what percentage of the germ content of the wheat can be recovered in the milling process?

A. Well, when you say "can", Mr. Thomas—

Q. Or is now being recovered, I will change that.

A. Yes, well, I have seen statements, or had certain millers make to me statements that they were recovering a quarter or more of the total germ in the mill at any one time, but I have never had acceptable data in my possession to the effect that that was being accomplished in American milling. And I still feel that the figure that I gave in my direct presentation, of ten per cent, is probably a fair figure for the mills that are recovering germ, some are not even recovering that much, if any.

1579

Q. What is the average purity of the germ being recovered?

A. That varies considerably again depending on the mill. I have seen samples that ran as low as 60 per cent purity, and others that ran above 85, and I imagine that a fair figure for the better qualities of flake germ are probably in the range of 70 to 75 per cent, about 70 per cent probably. There is quite a little endosperm and occasional bran flakes in the flake germ.

Presiding Officer Willcox: Is there any reason, Dr. Bailey, from the milling standpoint, why the long extraction flours of which you have been speaking should be more expensive to produce than ordinary straight grade flours?

The Witness: By long extraction we are now agreed upon this 76 to 77 per cent level?

Presiding Officer Willcox: Yes.

1580 The Witness: Except for the features that I brought out, in my opening presentation, namely the costs of assaying, and laboratory experience, and expense involved in control and meeting standards and specifications and so forth, there is no substantially enhanced cost known to me at the moment, if you keep your levels in that range.

Presiding Officer Willcox: You seem to be limiting that statement rather closely to that range. Are there other factors that dome in?

The Witness: As soon as you go above that range, and you have recourse to the regrinding and rebolting operations, then the mechanical expenses and others are going to be enhanced, and the general difficulties of operating the mill are increased.

Presiding Officer Willcox: Are there any further questions of Dr. Bailey?

The Witness: Could I make one further comment in response to your last question which has occurred to me, and that is another feature which has been perhaps overlooked this afternoon, and that is the added hazard of storing and merchandising these longer extraction flours, which doubtless are sharply enhanced as you get up into these higher levels of extraction. Insects are very fond of these long extraction flours, at least their life cycle
1581 is shorter, and the problems of dealing with insect infestation, and general spoilage become sometimes sharply enhanced when we get up into those ranges.

Cross-Examination by Mr. Goodrich.

Q. Doctor, in what form was the wheaf germ added to these breads, the three samples of which you have?

A. It was finely ground germ.

Q. Processed, dehydrated, or defatted or just freshly milled?

A. Freshly milled.

Q. Is the wheat germ an article of food now generally known and refeyred to in the consuming trade, or in the milling trade?

A. It is being sold fairly generally, in package form.

Q. The freshly milled wheat germ?

A. Well, both that and the processed germ.

Q. And how are they designated in their packaging, and in the merchandising?

A. That I am not competent to testify, I never surveyed the commercial products as they are sold in retail.

Q. Well, I don't mean by the commercial names, I was referring particularly to the name generally in which
1582 they are referred to in the trade. It is processed wheat germ, or wheat-germ, or do they have some other designation?

A. I am sorry, but I haven't seen enough types or brands to justify me in stating what it is. I am sorry.

Q. Thank you, I think that that is all.

Cross-Examination by Dr. Sherwood.

Q. Dr. Bailey, you have been discussing baking properties of some of these longer extraction flours, what is your view with respect to the desirability of using the oxidizing agents that are normally used in the preparation of flours and bread, to either bleaching agents which are used or bread improvers, which are oxidizers, such as bromates, to bring about the desirable improvement in dough handling properties and so on? I don't believe that you have touched on that. Do you regard that as desirable and advantageous?

A. I referred to that, Dr. Sherwood, very briefly in the closing part of my introductory remarks, and since I thought this over rather carefully, I think the safest plan is to reiterate it. Specifically, certain bleaching and improving agents may be of more service here relatively
speaking, than at present with white flour.
1583 May I interpolate this further comment, that I thing that that is based upon adequate scientific as well as technological experience, and if I were in the baking business, and had occasion to use these long extraction flours, I am confident that I would give more careful attention and consideration to that possibility of control even than the instance of standard patent flours.

Q. In discussing this in general terms, you talked about this situation of oxidizers. May I ask you specifically, would you regard bromate as a desirable addition to improve dough handling and baking properties, of these flours that you have been discussing?

A. I can very well believe that bromates, and re-agents

of that kind, might prove exceedingly useful and advantageous in the control of the bake shop manipulation of these flours."

Cross-Examination by Mr. Goodrich

Q. Doctor, have you had any experience in using bromates, potassium bromate, with these long extraction flours?

A. Yes, we have worked with them.

Q. Do you have any experience as to their reaction or the action of potassium bromate on any of the nutriants which you have taken the trouble to reincorporate?

1584 A. Yes, we had access to data that seemed to indicate that at least as far as thiamin is concerned, there was no substantial effect of the presence of substantial amounts of bromates, as well as several other typical reagents used in flour milling and bake shops upon that particular property, upon that particular ingredient of flour.

Q. And riboflavin, you have no evidence on that?

A. No, I don't recall at the moment any specific evidence on that.

Q. And there was no substantial reaction of the potassium bromate on the thiamin which you have reincorporated by using the long extraction flour?

A. No, or upon the synthetic thiamin deliberately superimposed upon the short extraction flour.

Q. I think that that is all.

Presiding Officer Willcox: I guess that is all, Dr. Bailey.

(Whereupon the witness was excused.)

Presiding Officer Willcox: Do you have another witness that you want to put on?

Mr. Campbell: No.

Presiding Officer Willcox: Would you prefer to adjourn now?

Mr. Campbell: Yes.

1585 Presiding Officer Willcox: We will adjourn then until nine-thirty o'clock tomorrow morning.

(Whereupon, at 4:15 o'clock, an adjournment was taken, to reconvene again the following morning, November 14, 1940, at 9:30 o'clock, a. m.)

1589 PROCEEDINGS.

Presiding Officer Willcox: We will come to order, please. Mr. Campbell, you wanted Dr. Wilder to testify first?

Mr. Campbell: Yes, we will yield to him, yes.

Whereupon DR. RUSSELL M. WILDER was recalled as a witness, and having been previously sworn, was further examined and testified as follows:

Mr. Goodrich: You have previously testified in this hearing, Dr. Wilder; your qualifications appear in the record, and you have some further statement to make at the present time?

The Witness: That is correct.

Mr. Goodrich: You may proceed in your own way.

Direct Examination.

The Witness: Mr. Presiding Officer, I ask to present my testimony wholly as a representative of the consumer, as an informed consumer, possibly. My reason for doing this is my interest in the problem of impfoving the nutritional quality of flour in the interest of better public health. I previously expressed my general philosophies, as they
1590 affect this problem, but I today wish specifically to give or state my opinions relative to the levels which flour must contain to represent a satisfactory food in the interest of public health.

My opinions regarding all of these levels are based on my study of the literature of nutrition, and that of medicine insofar as it involves nutritional problems, on individual experience in nutrition, both clinical and experimental, and on many recent conferences that have been held on this subject, including these previous hearings, and especially a meeting on October 28, of a sub-committee on nutrition of the National Research Council, of which I am Chairman.

Dr. Parran charged that committee in Chicago with proposing certain standards or levels of vitamin and mineral content of flour that would be desirable to strive for, and that committee met on October 28 and considered this question and reached certain conclusions. They have not reported on these conclusions, except informally, to Dr.

Parran, and a few others that were interested, and as yet they are not final, but only in the form of minutes which still since printing will have to be approved by the members of the committee, before they can be said to represent the opinion of that committee as a whole.

For that reason I don't feel justified in represent-
1591 ing that committee and what I say represents my own opinion based as I have indicated on experience and on these recent conferences.

This sub-committee of the Committee on Medicine, of the National Research Council, recommended a flour which to meet nutritional standards proposed in this recommendation should contain per pound not less than 1.66 milligrams of thiamin, 1.2 milligrams of riboflavin, 10 milligrams of nicotinic acid, or nicotinic acidamide, which is practically equivalent, and 20 milligrams of iron.

Now, I should like to consider then, or to discuss, various proposed additions to flour from the standpoint of the consideration that was given to these subjects in that committee meeting, and from the standpoint of my own opinion about them, and if it is agreeable I would like to start at the end and work back toward the beginning. In other words, with the minerals, and come back to the vitamins, closing with thiamin, which is the knottiest problem, as I see it, with which this hearing is confronted.

Mr. Goodrich: You are recommending only 20 milligrams of iron. Did you leave out a mineral or is that the only one?

The Witness: That was the only one that was considered.

Mr. Campbell: At this committee meeting?

1592 The Witness: At this committee meeting, yes.

To begin then with the minerals: Phosphorus has been thought of as an addition or additional ingredient to flour. In my opinion it is not in the interest of the consumer to add phosphorus to flour.

Calcium has been given great consideration in connection with this problem. As you noted, the sub-committee on nutrition did not mention calcium, and I believe it to be the consensus of medical opinion that there is no great need for calcium in flour. The Council on Foods of the American Medical Association, however, as I testified at the previous hearing, did recommend the addition of calcium to flour and the addition is recommended in the proposal of the Food

and Drug Administration. Personally I am sympathetic with this addition. I have seen a good deal of evidence of calcium deficiency in my practice, medical practice, and flour is a satisfactory carrier for calcium, and looked at exclusively from the point of view of the public interest, and the public health, certainly no harm would be done, and possibly much good, by the addition to flour of calcium. If it were done, I would like to accept the levels proposed by the Food and Drug Administration, namely, 200 milligrams per 6½ ounces, which would be 492 or approximately 500 milligrams per pound, with possibly allowing for a
1593 ceiling or maximum 50 per cent more than those figures. I understand that calcium now is used in an acid leavening of self-rising flour, and I have informed myself as to the amounts necessary for these purposes, and the figures that I have given you, I believe, would cover the requirements for those baking purposes, although I am considering this exclusively on the basis of the nutritional significance of these proposed additions.

Iron—or to put it this way—the addition of iron is included in the proposals of the Food and Drug Administration, on a level of 2½ milligrams per 6½ ounces. This level is based, or is being decided on, on the basis of a daily requirement of 10 milligrams.

As you heard from me, the Subcommittee on Nutrition set a higher level than this for iron. The matter is subject to discussion but personally I would not object, and would endorse the recommendation of the Food and Drug Administration regarding the level of iron, namely, 6.15 milligrams to the pound, and again I would suggest a ceiling of 50 per cent addition. That would raise the amount, or the maximum to 10 milligrams.

I have been told that there may be some procurement difficulties in connection with finding forms of iron that can be added to flour without affecting the color of flour.
1594 and I am informed that ordinary iron salts like ferric chloride would turn flour black, but that other less ionized forms of iron such as sodium iron sulphate, or iron pyro-phosphate can be added without affecting the flour unpleasantly, and that supplies, at least sodium iron sulphate, and iron pyro-phosphate, are adequate.

I should have mentioned iron pectinate, which has been used. It also is not ionizable and the procurement of it might be difficult.

I would now like to turn to the vitamins, and first con-

sider Vitamins A and C. I agree entirely with the recommendations or proposals of the Food and Drug Administration that flour does not represent a satisfactory carrier for Vitamins A, or C, and it is my opinion that it is not in the interest of the public health to add these two vitamins to flour.

Vitamin D presents a little different problem. The proposal of the Food and Drug Administration, as I understand it, was to add 100 units for 6½ ounces. This proposal is based on an estimated daily requirement for Vitamin D of 400 units, which is the same estimate that has been given by the Council on Foods of the American Medical Association, which I believe to be satisfactory.

Vitamin D is a necessary vitamin for children, as far as I can find out there is no satisfactory evidence that adults require more of it than they get from exposure to
1595 the sunlight, and it is, of course, a well-accepted fact that bread is primarily a food for adults. I have no opinion about the addition of Vitamin D. I would not strongly object to its inclusion as proposed by the Food and Drug Administration. Actually the matter has been discussed, and at one time was considered favorably the Council on Foods of the American Medical Association, of which I am a member.

We now come to the factors, or the vitamins in the so-called Vitamin B complex, and I would like to consider them in the order, nicotinic acid, riboflavin, and closing with thiamin.

The Food and Drug Administration proposal for nicotinic acid was 2½ milligrams for 6½ ounces, which would represent 6.15 milligrams per pound. My sub-committee on nutrition gave thought to this question of nicotinic acid, and their proposal, as I stated, was the addition of 10 milligrams of nicotinic acid to the pound. It is impossible to be dogmatic in this matter of nicotinic acid, for two reasons: In the first place, we can not say with positiveness, or with any degree of positiveness, what the minimum requirement is for this vitamin, and in the second place, methods of analysis for nicotinic acid have not been developed to the place where one can be sure just how much nicotinic
1596 acid is contained in many substances.

If nicotinic acid is added to flour, the policing will have to depend upon the examination of the mills where it is added, or analysis of the flour afterwards, for something that is made to accompany the nicotinic acid. I think that

that could be done. I think it is feasible. I think it is desirable. In my opinion it is in the public interest, to add nicotinic acid, and in the present state of our knowledge I would be entirely agreeable to accepting, or I personally would be agreeable to accepting the proposal of the Food and Drug Administration that the level of addition should be 2½ milligrams for 6½ ounces, which would represent 6.15 milligrams per pound.

The proposal of the Food and Drug Administration in regard to thiamin was the addition of 500 gamma, or micrograms, per 6½ ounces of riboflavin—I am discussing riboflavin now, or 1.23 milligrams per pound. This figure agrees exactly with the conclusions that we reached in our sub-committee on nutrition after much discussion of the subject, and hearing from authorities in this field of riboflavin research. My opinion would be that that would be in the interest of the public health, that these values proposed by the Administration are about what they ought to
be, or are what they ought to be. I would set a ceiling
1597 of 50 per cent more than the figures given, in other
words, I would set the minimum at 1.23 milligrams per pound, and the maximum at 1.83 milligrams per pound.

It is my opinion that if the standard is set up for a special flour to be called by some name which is to be decided on by others, some name such as Vita flour, or Minivita flour, or whatever name shall be chosen, that such a flour ought to contain riboflavin, nicotinic acid, iron, and thiamin as recommended by my committee on nutrition. However, in the matter of riboflavin, there are some difficulties about procurement, and it might inflict, or postpone a desirable program of improvement of flour to insist on the inclusion of riboflavin at the present time.

I want to go on record as being very strongly in favor of its inclusion. I believe it is in the interest of public health to have it included, but I would approve of its being included for the time being as an optional ingredient provided there was an understanding that a year from now or two years from now, or when the recommendation might be made by a suitable nutritional body, such as the Nutrition Committee of the National Research Council, or the Council on Foods of the American Medical Association, that it be included in, what is required to be included, is a
flour carrying this name, and complying with the
1598 definitions that are finally agreed upon.

That leaves us, I think, with only thiamin to con-

sider, and as I said I left that for the last because this matter of thiamin—and only here, apparently, is there any disagreement between me and the proposals of the Food and Drug Administration. I have expressed myself strongly at previous hearings against the acceptance of the idea that 250 international units represented the minimum requirement for thiamin, and at that time I proposed a minimum requirement of 500.

As I stated then, the opinion was based on some experiments that are under way at the present time, by my associates in the Mayo Clinic, and these experiments have convinced me that women weighing 55 kilograms are not fully normal on a measured in-take of 285 international units of Vitamin B_1 a day.

If you will take a pencil now and do some figuring with me, you will see that if a woman weighing 55 kilograms received 285 international units a day, a man weighing 70 kilograms would require 430 units a day.

Now, some men weigh more than 70 kilograms, and most men are not resting as much as the women who were the subjects of these experiments. Therefore, a minimum of 430 units for 70 kilograms, on the basis of these experiments, would be inadequate, and it would be desir-
1599 able to set a higher minimum than that, and I propose 500.

I made a slight error in this mathematics that I have just been recounting, or rather, in stating them, and I would like to repeat that. The women averaged 55 kilograms, and for men averaging 70 kilograms of weight—or may I start again.

The women averaged 55 kilograms and 285 international units of Vitamin B_1 was insufficient, whereas 333 was sufficient for them, barely sufficient.

If 333 units is barely sufficient for a woman weighing 55 kilograms, a man weighing 70 kilograms would require 70 over 55 times 333 or 430 units a day.

Now, that would be a man not doing any more work than these women who were clinically at what we speak of at room rest, they were not in bed; they were around but they were not engaging in any vigorous occupation. If 430 units or 450 to use round figures, is barely sufficient, is just enough to maintain a man in satisfactory condition, I think that we ought to have a factor of safety of 100 per cent, in the case of thiamin, and that would raise our level to 900 milligras—or 900 international units a

day for purposes of calculating what ought to go into bread.

It is my opinion that we must be more liberal with thiamin than with any of the other vitamins unless perhaps it is Vitamin C. This is because thiamin is a
1600 water soluble vitamin. It is rapidly used up or excreted when it is taken up into the body, and it is difficult to hold on to any of it, in storage, for use on a rainy day.

You know that you need more thiamin whenever any stress is placed upon the body, either for work or as a result of fever, or in pregnancy, or with certain other diseases, and to be on the safe side to carry your person through rainy days you must have enough to take care of them on the rainy days, because you have got nothing there that you have saved up from before.

Now, that being true, I think it is reasonable and in my opinion it is distinctly in the public interest and would be distinctly not in the public interest to do differently than accept a level of about 900 units for calculating what thiamin is to go into bread, and if I do that, then I find, and I adopt the method of calculation that has been followed heretofore, and in which I have been in agreement up to this point, of assuming that 6½ ounces of bread must provide one-quarter of that level which has been set as my daily requirement, and I arrive at a figure of 225 international units for 6½ ounces of bread, which is 500 units, or 550 international units for 6½ ounces of flour, which comes out to 500 or 550 units that was the recommendation of my subcommittee on nutrition for the content of thiamin in bread.

1601 That 6½ ounces of flour must provide one-quarter of 900 international units, or 225 international units, and a pound of flour then would need to provide from 500 to 550 international units, and I would again think, and it would be my opinion that it would be in the public interest to make that the minimum and to set as a maximum a figure representing 50 per cent more than that or 775 international units per pound of flour.

Now, my committee discussed the question of the expense of such additions of vitamins to flour and all of us felt strongly that we must make every effort to avoid increasing the costs of this staple food which is the staff of life, more particularly for those in low income groups, and if the cost of it is increased, people that need it most

won't get it. For that reason they feel strongly, or for that reason I feel strongly, that it is in the interest of the public health to permit this flour which is to carry this distinctive name, to be made either by processes of milling which will retain the vitamins normally in the wheat, either in whole or in part, to reach these levels proposed, because such flour would be a cheap flour.

To add these vitamins to a flour from which you have previously removed them, as you would have to do if you tried to make a patent flour, conforming to these standards, would at the present costs of these sub-
1602 stances bring the price up from 35 cents to 75 cents a barrel of flour, depending on whether or not you included the riboflavin as well as the thiamin. The nicotinic acid is very inexpensive, and so is the iron. However, when you finally reach those levels it would be my opinion that you would have a flour that would be in either case a very valuable flour nutritionally, and that such flour, that it is in the interest of public health to promote the use of such flour.

I want to express serious objection to those who have pretended that synthetic vitamins are in any way inferior to natural vitamins. My opinion, you will find, will be shared by everybody with training in chemistry, and biology, that there is absolutely no difference between thiamin prepared synthetically, and that extracted from natural sources of thiamin, and the same applies to riboflavin and any of those vitamins that have been prepared in pure form. I think it is important to have that in the record, for the reason that people are expressing, uninformed people are expressing contrary opinions about that matter.

To conclude, then, it is my opinion that a flour which is to carry a distinctive name indicating that it is enriched or forfeited or in any way has had vitamins and minerals added to it, that such a flour ought not to be given
1603 such a name unless it contains those vitamins which today present no difficulties in procurement, and also contains iron. In other words, I would say that such a flour should contain thiamin, nicotinic acid, and iron. In my opinion it would be only fair to make riboflavin an optional ingredient with the understanding, however, that this definition may be subject to revision as soon as procurement of riboflavin is satisfactory, that I would then approve of including as optional ingredients cal-

cium and Vitamin D, and I believe that that covers the list of the things that are being proposed, and I believe that that is all that I have to say, sir.

Mr. Campbell: Before we begin the cross-examination, you used the term "bread" on a few occasions here, where you meant flour, is that correct, in some of your relationships and calculations?

The Witness: I mean flour wherever I said bread.

Mr. Campbell: That is what I wanted.

Cross-Examination by Mr. Goodrich.

Q. You consider it not to be in the interest of public health, or in the interest of consumers, to permit the fortification of flour with B_1 alone or with riboflavin alone, or with calcium alone, or iron alone or any of these substances used singly and not in the combination which
1604 you have suggested?

A. I would disapprove of that.

Q. And the reason, please, sir?

A. I would disapprove of that on the ground that it is recognized that the public is suffering from a lack of many of the constituents of what is called the "B-complex," and that as much should be done about that as procurement problems permit and there is no difficulty in procurement of nicotinic acid, nor of thiamin, nor of iron.

Q. Is it true, that the existence of a diet deficiency disease, manifestations of which are the symptoms of beriberi, for instance, would likely be accompanied by other diet deficiency diseases, such as pellagra, or scurvy, when the diet is insufficient to such an extent as to cause one diet deficiency disease, is it true that other diet deficiencies are likely to exist?

A. That is absolutely true. It is practically impossible to find a single dietary deficiency in clinical practice, one has to go to the extreme elaborateness of such an experiment as I described at the last hearing, to see a pure thiamin deficiency, for instance.

Q. Can you give for the record, please, sir, the basis upon which your committee decided that it was not in the interest of consumers or in the interest of public health to permit the addition of phosphorus to flour?
1605 A. Phosphorus was not discussed, I think, in our committee. My own opinion about that is that phos-

phorus, supplies of phosphorus are generally abundant in all diets, even in a poor diet, and there is no need for more phosphorus in the diet, and it was upon that basis that I considered the addition of phosphorus not a necessary thing from the point of view of the nutrition of public health.

Q. What is the basis upon which the consensus of medical opinion has been established, that calcium is not a proper addition in flour?

A. That perhaps is stating the question a little more vigorously than it should be stated.

Q. You may qualify it in any way you care to.

A. I don't think that I said that medical opinion was opposed to the addition of calcium to flour. I said that the Council on Foods of the American Medical Association had actually approved the addition of calcium to flour. My own opinion in the matter is that, I can't speak for the profession, in other words, other than what I have said, my own opinion is that milk and cheese are the best sources of calcium, that they are very good foods, and the consumption of those foods ought to be encouraged, and I fear if people could get their calcium too easily it might be difficult to promote the consumption of
1606 milk and cheese, and the consumption of milk and cheese is important in the public health interest for more reasons than just its calcium content.

Q. In referring to the several proposals of the Food and Drug Administration, you refer to the testimony by Dr. Nelson at the original hearings, held starting September 9. I believe he testified some time during that week, of September 9?

A. I refer to that testimony which I read, but I refer specifically to the printed proposals in the Federal Register.

Q. On the special dietary foods?

A. Yes.

Q. I believe the special dietary foods proposals were the ones establishing or proposing minimum daily requirements, and it is to that which you refer, and the 6½ ounce daily consumption also referred to by Dr. Nelson at the original hearings was involved in your calculations here?

A. That is correct.

Presiding Officer Willcox: And you base your calcula-

tions on the assumption all the way through that that represents about a quarter of the caloric intake?

The Witness: Yes, sir. My understanding is that the testimony given by Dr. Nelson included refer-
1607 ences, or included the assumption that 6½ ounces of flour should carry one quarter of the minimum requirement for the day, is that correct?

By Mr. Goodrich:

Q. Can you give for the record any additional evidence, if there is none in the record at the present time, with respect to Vitamin D deficiencies in the American dietary today?

A. The only way I can talk about that is from my knowledge of the literature. It is well established that children suffer from rickets unless they are provided with more Vitamin D than they get in their foods, that cod liver oil administration can prevent the occurrence of rickets, and that the use of milk, that is fortified with vitamin D can prevent the development of rickets. I have yet to see any clear evidence of a similar character that adults suffer from a lack of Vitamin D.

Q. What age groups are so affected by Vitamin D deficiencies, if you know?

A. Principally infants, up to two or three years of age, but I am not an authority on that. Children may also be affected up to eight or ten years of age, I know, from personal experience, but certainly it is a condition that affects principally infants.

Q. The flour consumption of an infant would be
1608 practically negligible, would it not?

A. Yes.

Q. And I assume that the same would be true of a child up to eight or ten years of age, with some differences, of course?

A. Yes. You could answer that as well as I could, of course, I don't know what the flour consumption of children is with any precision.

Q. You are familiar with typical diets in that age group?

A. Somewhat, yes.

Q. And what percentage of the caloric intake is supplied by flour, if you can say?

A. Well, I can't say exception for a special group of children, with diabetes, that I know about, but in them

between the ages of three and ten, I should say that the consumption of flour was in proportion to the consumption of flour by adults.

Q. Well, in a child suffering from such a condition, the flour in-take would be increased, would it not, over the average?

A. No, in a child suffering from such a condition, maybe the flour in-take would be somewhat less than the average, although our tendency nowadays is to provide our diabetic patients with diets that are pretty close to the
1609 diets of normal, healthy people.

Q. Let me see if I understand that. Upon that assumption, and upon your information with respect to diets of special groups, would you say that the dietary of a child, and/or an infant, would have one-fourth of the caloric in-take supplied by flour?

A. I said that it might well have that much, yes. May I add that in the case of children it is particularly important that we have a continued milk consumption and with a continued milk consumption they would receive the Vitamin D that they needed, if they used a Vitamin D milk, which I would like to encourage.

Q. Proceeding to the B complex, what evidence can you give us, if any, with respect to deficiencies of nicotinic acid, in the American dietary?

A. Nicotinic acid as has been shown by Elva M. Fordyce and Pease and Jolliffe, and Siddenstriker, and David Smith, and many others, protects against diseases of the tongue and skin and gastro intestinal lesions of the disease known as pellagra, and it is very important that it should be obtained, to protect the public and the people from this disease. There is much more of that disease in the South than there is in the North, apparently, but we see cases of pellagra in the North right along, and as our Southern colleagues have been educating us, we see more and
1610 more of it, and in my own hospital in Rochester, we see a case of pellagra, or incipient pellagra, every so often. I don't know how many cases we will see, but we see cases with such frequency that in my opinion the disease is not limited to the South but has spread over the country.

Q. Is the disease pellagra restricted more or less to any income group or age group, or anything of that kind?

A. Accoriding to the literature it is found more in the

low income groups in the South. Many of the cases that we see in the North are alcoholics, but by no means all of them. The alcoholic is not protected by his pocketbook against pellagra.

Q. Is the deficiency disease pellagra confined to those groups which likely will be benefitted by the fortification with nicotinic acid of a flour?

A. No, that is not confined to those groups, because pellagra is seen in people with high incomes, that are not alcoholic, but more of it occurs in the poor, and the poor depend more than the rich on flour for their food.

Q. Would there be any assurence in your opinion that fortification of flour, costing from 35 cents to 75 cents per barrel in excess of ordinary flour, would reach these groups now suffering or likely to suffer from the deficiency disease, pellagra?

1611 Mr. Campbell: Just a minute, you said 35 cents to 75 cents, per what?

Mr. Goodrich: Per barrel.

The Witness: In my opinion people in the low income groups ought to be encouraged to buy flours which by milling processes retain those factors, and therefore don't cost that much or won't cost that much. It is also my experience that it will be possible to do something by a national educational program to encourage the use of these flours, with a flour of the type that we are talking about, and finally, it occurs to me that, that is the stamp plan might be mobilized to help the distribution of such flour. That is the blue stamps being good, we will say, only for a flour which carries the endorcement of the nutritional program, when that finally is developed.

By Mr. Goodrich:

Q. What was the success, if you know, of the program of supplying yeast to these low income groups in the South? Are they using it and has that any substantial effect in the reduction of pellagra?

A. I haven't any information that is worth anything on that subject.

Q. What are the recommendations of your committee with respect to nicotinic acid content of fortified flour, based upon?

1612 A. They were based on an estimated daily requirement of 25 milligrams, I think, but as I stated before,

none of us felt prepared to be dogmatic about that minimum requirement.

Q. Proceeding now to thiamin, what percentage of the American dietary now supplies 900 international units per day, of Vitamin B_1?

A. Almost none.

Q. And that in turn would mean that almost none of the American people are getting that amount of Vitamin B_1 each day?

A. That is correct.

May I supplement that statement? The inference from that answer is that either all of us are suffering from thiamin deficiency, or that this proposed level of requirement is much too high. That inference is not justified. None of us in this room, presumably, is suffering from gross thiamin deficiency, and probably not many of us, although I suspect a few are suffering some effects of an inadequate intake of thiamin, that they don't recognize as a disease.

But the point is that any of us in this room, should we be subjected to unusual conditions of stress, might need that much, and under the conditions of our present food economy we don't ever get it, and I feel myself con-
1613 fident that many patients in hospitals suffer protracted convalescence as a result of inadequacy of their thiamin in-take during the period of added stress involved in the situation that took them into the hospital.

Q. Youd minimum daily requirements are substantially higher than those suggested by other writers in this field, are they not?

A. They are twice as high as the levels set by the Food and Drug Administration of 250 international units a day. The technical commission of the League of Nations set the level either 300 or 333, I think it was 300 international units, as a minimum requirement. In all of the books up to the last two or three years, this value of 300 has been generally taken as the minimal requirement for Vitamin B_1 but in recent conferences with people in the nutrition field, it appears to me that almost everybody is coming around to the recognition that that level set by the Technical Commission of the League of Nations is too low.

Sir John Ohr, and the other members of the Scientic Food Committee of the Medical Research Council in England have taken that position, that that level is too low, and as I state, many people have expressed the opin-

ion—Dr. Williams testified in previous hearings, that he felt that that level was too low, and Dr. Carlson so
1614 testified, and I personally feel that these few controlled experiments prove that such a level is too low, to be on the safe side.

Q. By controlled experiments, you mean the ones reported in the Archives of Internal Medicine, Volume 66, No. 4, I believe, in which you participated?

A. I refer to those, and likewise to similar experiments on a larger group of subjects that is now under way.

Q. Would you say that a minimum daily requirement of 900 U. S. P. units is higher than that suggested by most of the other nutritionists that have written on the subject?

A. Yes, that is higher than is proposed by anybody, as a minimum, and I am not proposing it as a minimum. I am proposing 500 as a minimum, and proposing, however, in view of these factors about thiamin that I related, namely, the failure of facilities for storage, and increased need of it in times of stress, that the factor of safety in the case of thiamin ought to be higher than in the case of the other vitamins, and that therefore that factor of safety ought to be such, ought to be higher than in the case of the other vitamins, and that therefore that factor of safety ought to be such as to be 80 per cent instead of 50 per cent which raises you to 900 as the only safe level to do any calculating on if you are thinking of bringing thiamin back to the people.

1615 Q. In all of your calculations you have referred to a ceiling of 50 per cent higher than the minimum suggested by you, and I believe that that is a safety factor which you have referred to, I believe, in the past, as a minimum plus this safety factor, is it not, if you can explain that for the record, please, sir?

A. Well, I feel strongly, and in fact it is my opinion, that the public interest demands that we set a ceiling to these fortifications. I think that we are all agreed that we don't want foods to become simply carriers of medicines, even such medicines as thiamin, which really are forms of food. I feel that we should set some ceiling and in the case of most of the vitamins I think a ceiling 50 per cent higher than the level suggested as a minimum would be sasisfactory, in the case of thiamin I feel that that factor of safety ought to be greater, and the ceiling ought to be set at a somewhat higher figure.

Q. In adding the several vitamins to flour, in what form do you suggest the addition of nicotinic acid?

A. It can be added as nicotinic acid, or as nicotinic acidamide. The amide is a little more expensive and the procurement is a little more difficult. In the amounts proposed, I would think that the proper thing to do would be to use nicotinic acid, which is cheap and easy to procure.

Q. In the pure form?

1616 A. In the pure form, yes, sir.

Q. And riboflavin, what form?

A. I personally have no objection to the use of a concentrate of riboflavin, obtained by the butyl distillation. It is a butyl fermentation. It is a process that has been developed and is already in practical use, by one of the large millers, who are distributing a flour containing riboflavin, riboflavin being added in this form, and it is a feasible thing to do except that at the present time the amount of that material is limited, and it is because of that limitation that I suggest that temporarily we include riboflavin in the lits of optional ingredients rather than in the list of "must" ingredients.

Riboflavin can also be added in synthetic crystalline form, and the process of its manufacture is expensive, and to add it in this way will probably for a long time be expensive. I am informed, however, that the actual cost of bringing a patent flour up to the level we propose would not be today much more than to bring the content of thiamin up from the patent flour level to the level we propose. The reason for this is that the amount of riboflavin necessary to add would be smaller than the amount of thiamin necessary to add. However, in the future, it is my opinion that the cost of thiamin is capable of being materially lowered, and I am not so sure about that being true of the cost of riboflavin.

1617 Q. What purity and potency requirements should be made in defining a riboflavin concentrate?

A. I can't answer that question.

Q. You don't have any suggestion to make in that connection?

A. I have not looked into that question at all.

Q. And do you know the carrier, in which the riboflavin is contained, in this concentrate which you suggested?

A. I have some information about that but I don't

know that it is worth while introducing that into the record. (Reading):

Riboflavin Concentrate is made from a mash consisting solely of food grade grain (any of the common grains can be used) and pure well water which passes specifications for drinking water supply. No chemicals of any kind are added to the grain mash, and its only treatment comprises a thorough cooking in clean vessels by means of steam, under sufficient pressure to completely sterilize the mash. This is followed by fermentation in sterile vessels by means of a strain of butyl alcohol-producing microorganisms. It is essential that sterile conditions be maintained throughout the process, and adequate inspection, both microscopic and macroscopic, is maintained to effect this end.

1618 The microorganisms employed to carry on the fermentation constitute a strain of butyl alcohol-producing microorganisms originally isolated from cereal grain, and preserved in a dry, pure culture. These microorganisms are widely distributed in nature and may be found on all fruits, vegetables and grains which have not been treated to render them sterile. A very small amount of the culture (approximately 0.01 gram) is incorporated in sterile grain mash in a test tube, and after the microorganisms have been allowed to grow for a number of hours, the fermenting mash is transferred to a larger amount of sterile grain mash. This process is continued until sufficient culture is available to start the fermentation of a large volume of sterile grain mash in the commercial-scale fermentation vessel. The large fermentation vessels are thoroughly washed and sterilized by means of steam under pressure, and cooled with sterile air prior to filling with mash, which has been cooked and cooled in a sterile system. The culture, which is added to the sterile mash in the large-scale fermenting vessel, is subjected to microscopic examination and other accepted control tests to insure that it is free from contamination by other microorganisms, and this control is affected also throughout the fermentation of the mash in the large-scale vessel.

1619 The mash is allowed to ferment in the large-scale vessel until the maximum concentration of riboflavin is obtained, at which time the solution containing the water-soluble vitamins is separated from the solids fraction of the fermented grain mash, and is sterilized by means of steam under pressure. The sterilized liquid is

then evaporated, under sterile conditions, to a thick syrup, which is subsequently dried and ground to a fine powder under carefully controlled conditions.

It may be seen that throughout the entire process the original raw material, i. e., food-grade grain, has been subjected to no chemical treatment, and has had nothing added to it except pure well water and a very minute amount of butyl alcohol-producing microorganisms.

The product described above contains 4500 micrograms of Riboflavin per gram, and other factors of the Vitamin B complex in the following approximate amounts:

B_1	30 micrograms;
B_6	25 micrograms;
Pantothenic Acid	700 micrograms.

The product may, therefore, be regarded as a natural Vitamin B concentrate. It has the following approximate composition as indicated by chemical analysis:

Moisture	3.5 per cent;
Protein	37.0 per cent;
1620 Fat	0.2 per cent;
Ash	14.0 per cent;
Fiber	0.3 per cent;
Nitrogen free extract	45.0 per cent;
Total	100.00 per cent.

By Mr. Goodrich:

Q. Can you explain what that statement is that you have read, just so the record will show that you have read it into the record?

A. I have read into the record the above statement of the method of manufacture and description of a riboflavin concentrate as made by the Commercial Solvents Corporation.

Presiding Officer Willcox: The statement was prepared by the company, or by a representative of the company?

The Witness: This statement was received from the company.

Presiding Officer Willcox: We will take a recess for a few minutes.

(Recess.)

Presiding Officer Willcox: We will proceed.

By Mr. Goodrich:

Q. Dr. Wilder, it has been suggested that Vitamin
1621 B_1 concentrates be permitted as an acceptable method of fortification of flour with Vitamin B_1. This as I

understand it is in the form of yeast or something of that kind. Could you elaborate on that and tell us what those concentrates are that are in general use today?

A. The only concentrated form of Vitamin B that I know about, being used in flour, is yeast, and particularly a form of yeast that has been grown on a paradine culture medium so as to make it very rich in Vitamin B_1. This is a product, I think, of the Fleishman Company, developed by Dr. Frey. I don't know that that can be added to flour, excepting in the process of making bread.

Q. Have you had experience with adding B_1 in the form of processed wheat germ?

A. Yes, I forgot that when you asked the question. Wheat germ contains about—I have forgotten now, but it does contain, or it is a source of B_1 in fairly concentrated form, and it is used for addition to flour in larger amounts than the flour, or than the wheat normally would contain, and thereby attempting to raise the Vitamin B_1 content of the flour. It can't be added in sufficient amount to meet the levels that I think that flour ought to reach, without interfering seriously with the baking quality of the flour.

Q. Then if that be used it would probably have to
1622 be used in connection with thiamin chloride or some concentrate other than the wheat germ?

A. If that were used it could not be depended on exclusively and something else, or additional, would have to be used, too.

Q. Is the processed wheat germ of sufficient Vitamin B_1 activity to be what you generally speak of as a concentrate?

A. It is a concentrated source of vitamin, yes, but not as concentrated, for instance, as this high vitamin B yeast, by any means.

Q. Or this riboflavin concentrate that you have just spoken of?

A. It would be much less than that.

Q. It would be in a different class from that type of concentrate?

A. I think it would be in a different class so far as B_1 is concerned than that type of concentrate.

Q. Is there an understanding in the nutritional field of the meaning of "a concentrate?" When you speak of a concentrate among yourselves, do you understand that to have any degree of potency or purity or anything of that kind, or is that a term loosely applied?

A. I think the term "concentrate" is rather loosely used. "A concentrated source of," would apply bet-
1623 ter to something like ordinary yeast, or this wheat germ. The concentrate as used by the medical profession, at least, is usually an extract, represents an extract of some sort, for instance, an extract of rice polishings is a concentrate of Vitamin B.

Q. And would you place the two sorts of things in different classes?

A. I think if we wanted to be careful in our language we ought to, myself.

Mr. Goodrich: I think that that is all. Thank you.

Cross-Examination by Mr. Campbell.

Q. Doctor, in your direct testimony you estimated the cost of the added nutrients, which you have recommended, at about between 25 and 75 cents per barrel. In making these estimates, did you take into consideration the cost of feeding in and control of these ingredients in the milling process, or just the bare cost of the nutrients?

A. My estimate was based on the present market cost of these factors, as I have heard them during the last week or two, and did not take into account any added manufacturing costs that might be involved.

1624 Q. Now, the suggested minimum levels for iron and calcium are quite small, are they not? I mean in amount—with relation to the per pound of flour? I don't mean by that to suggest that you haven't got them high enough, but what I wanted to ask you, is would you have any objection to increasing the ceilings on iron and calcium to a figure more than 50 per cent of the minima figure that you have suggested?

A. No, I would have no serious objection to increasing those ceilings. Indeed, I can see certain reasons why they might advantageously be set at a higher level than I gave, for instance, in the case of calcium. It might be desirable to go to a somewhat higher level for technical reasons. I was testifying only from the standpoint of nutritional desirability. If there are technical reasons for going higher, there would be no nutritional disadvantage in doing so, up to some reasonable level which, however, I think ought to be clearly defined so that somebody can't go away above that level.

In the case of iron, I might add to that statement. I

could see some possibility, although not perhaps provable, advantage in setting higher figures, and I certainly would not object to making the ceiling optionally higher if that involved advantages other than nutritional advantages,

because it could certainly not be nutritionally dis-
1625 advantageous to use as much iron, for instance, as four times 6.15, as a minmum, and I would not like to go higher than that. That would put your minimum at 6 and your maximum at 24, your minimum of 6.15 and your maximum at 24.6.

I can't see any nutritional disadvantage, and I am thinking of these things exclusively from the point of view of the public health, in the matter of public health.

By Mr. Goodrich:

Q. That is 6 to 24 milligrams of iron for one pound of flour?

A. Yes, for one pound of flour.

Mr. Campbell: I think that that is all.

Cross-Examination by Mr. Sherwood.

Q. In your testimony you mentioned the use of iron compound, as optional ingredients, and mentioned among others iron phosphate.

You are aware, of course, that flour contains phosphorus, naturally, and that there are phosphated flours now on the market, and in consideration of those two factors, and your mention of iron phosphate as a source of iron, would you have any objection to seeing phosphorus included as an optional ingredient?

A. No, I would have no objection to increasing the maximum phosphorus, Mr. Sherwood's question is an
1626 illustration of exactly the type of thing that I had in mind in answering the previous question.

I have been considering these matters exclusively from the standpoint of their nutritional advantage. I don't see any nutritional advantage in adding to the phosphorus intake of our diets.

On the other hand, there would be no nutritional disadvantage in adding moderately to the phosphorus intake to such an extent as would be necessary to permit the use of some—the use of a technical process like that involved in using iron pyrophosphate, for instance; in order to get the iron, the phosphorus has to accompany it.

To cover this problem, I would suggest that if phos-

phorus is made an optional ingredient, and if a minimum is established for it, that the maximum ought to be roughly proportional to the maximum that you set for calcium.

Q. One other question. You would approve iron citrate as a source of iron, in this list of optional ingredients, as well as iron phosphate, and others that you mentioned?

A. I have no reason to disapprove of the use of iron citrate. It is actually being used by your people in the manufacture of that special Vibec bread, as I understand, and I believe that nutrition experiments indicate
1627 that its absorption is satisfactory. It is a non-ionizable form of iron, and for that reason very desirable because it doesn't color the flour.

Q. You meant to refer to flour instead of bread?

A. Yes, I meant flour.

Cross-Examination by Dr. Strowd.

Q. Doctor, I was in and out during your testimony: Did you name the various compounds which you believe were acceptable? He just asked about iron phosphate, and iron citrate. Did you name any calcium compounds that you felt would be acceptable as sources of calcium?

A. No, sir. I named no calcium compounds.

Q. I would like to ask you upon other questions, please, sir.

We have a practical problem in using nicotinic acid in flour. The lay mind confuses the idea with putting cigarettes in it. It is funny, but nevertheless it is serious too, and one suggestion has been made as an alternate name, antipellagra factor. Would that be acceptable, or would you accept a similar name? I refer now to labeling, to the label on the bags.

A. It would be acceptable to me. I don't know how much that would help.

Q. Would that be properly descriptive?

A. In my opinion it is a synonym.

1628 *Cross-Examination by Dr. Scott.*

Q. Dr. Wilder, the Council on Foods of which you are a member accepts vitamin D milks as a food carrier for vitamin D, is that true?

A. That is correct, yes, sir.

Q. Do you know how much of the total milk supply that is consumed for beverage purposes is fortified with vitamin D?

A. I can not give you the figure.

Q. You recognize that practically all of the vitamin D milk that is sold is sold in large cities, is that right; there is very little distribution in small cities?

A. That s very true.

Q. And that in rural populations or rural districts they do not have access to vitamin D milk at all, is that true?

A. I suppose that that is true.

Dr. Scott: That is all.

Cross-Examination by Dr. Lee.

Q. Dr. Wilder, did your committee consider the addition of milk to bread?

A. Our committee did not concern itself with bread.

Q. Is dry skim milk a pretty good source of ribo-
1629 flavin?

A. Very good source, yes, sir.

Presiding Officer Willcox: Are there any further questions?

Mr. Goodrich: I would like to ask one more question.

Cross-Examination by Mr. Goodrich.

Q. The names nicotinic acid, riboflavin, thiamin, are common and usual names of these vitamins, are they not, in the "B" complex?

A. They are the accepted nomenclature by the authorities.

Q. There has been in the past?

A. I think the public still talks about vitamin B-1 and vitamin B-2, and the pellagra preventing factor.

Q. And there has been, in the past, I believe, some discussion among the experts as to proper terminology, has there not?

A. Every one of these new compounds when it comes up involves a hearing something like this one before a name is decided on.

Q. Then has thiamin been decided on as the proper name, common and usual name, for what sometimes is referred to as vitamin B-1?

A. That is my understanding, thiamin hydrochloride.

Presiding Officer Willcox: Decided upon by whom?

1630 The Witness: Well, that was the decision of the American Chemical Society, and the Council on Pharmacy and Chemistry of the American Medical Association. Is that not right, Dr. Williams?

Dr. Williams: The reverse, I think, in order.

By Mr. Goodrich:

Q. There is a committee on vitamin nomenclature existing somewhere. I don't know exactly where it is. Can you tell us where that committee is?

A. Well, I know, but I have forgotten. I couldn't state exactly.

Q. Then, in using pellagra preventing factor, or anti-pellagra factor, you would not be using the common and usual term which has been adopted for these factors, for the vitamins?

A. That is correct, and in using that factor, you would encounter some opposition from the Council on Foods and the Council on Pharmacy of the American Medical Association, who have taken a stand against the use of a name for a drug, which suggests its therapeutic application, and of course pellagra preventing very definitely suggests not only that it prevents pellagra, but also may cure pellagra. That objection has been the cause of the principal discussion in the naming of these vitamins.

For instance, thiamin; it was called "aneurin",

1631 which suggests that it might be used for neuritis, and objection was taken to that name, on that score.

Mr. Goodrich: I think that that is all.

Presiding Officer Willcox: Are there any other questions of Dr. Wilder?

(No response.)

(Witness excused.)

Mr. Goodrich: Dr. Sebrell of the Public Health Service is here, and has an oppointment at 12:30, and he has another appointment at 3 o'clock, and he is leaving town tonight, so that we would like to work him in right now.

He appears as a witness on behalf of the Public Health Service.

Whereupon, DR. WILLIAM H. SEBRELL, JR. was called as a witness by and on behalf of the Public Health Service, and having been first duly sworn, was examined and testified as follows:

Presiding Officer Willcox: What is your name and your educational background?

The Witness: William H. Sebrell, Jr., doctor of medicine from the University of Virginia in 1925, and I am now a surgeon in the United States Public Health Service, in charge of the investigations on nutrition at the Na-
1632 tional Institute of Health. I have been there for several years.

I have been a member of the League of Nations Technical Commission on Nutrition. I am a member of the Committee on Nutrition of the Pan-American Sanitary Bureau. I belong to a number of scientific organizations, such as the Society for Clinical Investigations, the Society of Biological Chemists, American Chemical Society, American Institute of Nutrition, and similar bodies.

I have been engaged exclusively in research work in nutrition for the United States Public Health Service since 1928. I have conducted a number of experiments, published a number of original articles, especially in the field of the vitamin B complex, specifically riboflavin and nicotinic acid.

Mr. Goodrich: I think that that is all right to qualify you.

Now, you have some statement to make with respect to vitamin and mineral additions to flour, and you may proceed in your own way to discuss them.

The Witness: The consensus of medical opinion, and the results of dietary surveys, in this country, indicate that dietary deficiencies and dietary deficiency diseases are very common, and in the more or less extent involve a large
1633 percentage of our population which has been estimated by some people to be as high as 30 to 40 per cent of the population.

There are various reasons for this situation, which I don't believe that I need to go into at this time. This situation, the existence of this situation, indicates to me that we seriously need some method of preventing it, and assisting in correcting it.

Flour being a very common and universal article of diet

in this country is in my opinion a proper place to add vitamins and minerals for the purpose of preventing these deficiencies, and I think it is in the public interest, in the interest of the health of this nation, that we have a special standard for a vitaminized or enriched flour. It is also in the public interest, and in the interest of honest and fair dealing that specific figures should be set in this standard for the various things which are to be added, and I will take up those things separately.

As a principle to go on, in arriving at these figures, I am in agreement with the testimony of Dr. E. M. Nelson, that we can use as a basis for calculations one-fourth of the daily requirement, and his testimony shows how he arrived at 6¼ ounces of flour as representing an average daily consumption of flour, and therefore 6¼ ounces should
1634 carry about one-fourth of the daily requirement of these various things as a minimum figure.

I am also in agreement with Dr. Nelson and Wr. Wilder that it is necessary to have a maximum figure, and I will discuss that maximum figure and the reasons for it under each item separately.

I feel that, or it is my opinion that from the point of view of the interest of the consumer, and the public health, a variety of ways, or variety of methods of obtaining this level should be permitted. The point of principal interest is the level of the substance in the flour and not the method by which that level is obtained, so long as there is nothing harmful in the method of obtaining it.

And I would also stress the point mentioned by Dr. Wilder that no distinction should be made between natural sources of vitamins and synthetic sources of vitamins. For that reason, among others, I don't think that we should have a separate standard for a synthetically fortified white flour, or a lightly milled flour.

Any special flour which is to be sold or represented for the purposes of correcting or preventing dietary deficiencies, should meet the standards being proposed for this product. Specifically it is my opinion that the product should be required to carry thiamin, nicotinic acid; and iron, that optional ingredients should be calcium and
1635 vitamin D, and I would support the position taken by Dr. Wilder that as a matter of principle, riboflavin should be required, but because of the practical difficulties of obtaining a sufficient supply of either pure riboflavin or

riboflavin concentrate, that it would be unreasonable to require riboflavin as part of the standard at this time. And that should be permitted as an optional ingredient with a definite understanding that at some future date it is to be included as a required ingredient, when the production needs can be met.

I would have no objection to phosphorus as an optional ingredient. However, I do not believe that the advertising or representations, as to the beneficial effect of this flour should be based on its phosphorus content. Furthermore, it is my opinion that flour is not a suitable vehicle for the carrying of vitamins A and C, and in the public interest they should not be permitted, either as required or optional ingredients. The level or quantities, therefore, which I would propose are as follows:

For thiamin, a minimum of 550 International units per pound of flour, with a maximum of 775 International units of thiamin per pound of flour.

Mr. Goodrich: Let us calculate that down to 6¼ ounces; how much would that be?

1636 The Witness: That is 40 per cent; 225 as a minimum to 310.

It is my opinion that this level, this minimum level which is proposed here should not be interpreted in terms of the minimum human daily requirement, as given by Dr. Nelson, in his testimony. There are differences of opinion as to what constitutes the minimum daily requirement. We are concerned here with supplying a product which in the public interest will supply a sufficient amount of thiamin to be of significance in preventing the symptoms of thiamin deficiency.

There will be a certain amount of destruction of the thiamin in flour, in its handling in the home, and various baking and cooking processes. We should take that into account, and we should not base our level on the absolute minimum daily requirement. We should concern ourselves rather with a level which will prevent any symptoms of deficiency.

I believe, therefore, that this level of 550 international units per pound of flour is a reasonable level, and adequate level, and not an excessive level; but one which will be of real health significance.

I believe anything less than this would be too small to satisfactorily do the job. The maximum figure which

I have proposed represents simply a 50 per cent
1637 increase over the minimum figure, and I suggest that merely for purposes of tolerance. I do not believe that anything is to be gained by giving a quantity of thiamin greatly in excess of this figure. I think that we are dealing with what I would call an optimum, or the most desirable level in the 550 International unit figure.

In the case of riboflavin, my opinion agrees with that expressed by Dr. Nelson, that the minimum quantity should be 1.22 milligrams per pound, as a minimum, with a maximum of 1.83 milligrams per pound. That is via a minimum of 500 micrograms per 6½ ounces, or 750 maximum.

This maximum figure again being a 50 per cent increase over the minimum, it is for purposes of tolerance. I believe that that minimum figure of 1.22 milligrams is a reasonable figure, and one which is adequate. I believe any amount less than this would not be in the best interests of the consumer, in that it would be too low to prevent the development of symptoms.

But I will add further here, or rather repeat, that I regard riboflavin as an optional ingredient only because of the difficulty, or the impossibility of obtaining adequate amounts of it, making it at this time unreasonable that we should require riboflavin, with a definite understanding that it would later be a required and not an optional ingredient.

1638 In the case of nicotinic acid, I again agree with the testimony of Dr. E. M. Nelson, and would propose a minimum figure of 6.15 milligrams per pound, or 21 milligrams per 6½ ounces, with a maximum of 10 milligrams per pound.

I believe that this should be a required ingredient as Dr. Wilder indicated in his testimony. Clinically we see multiple deficiency diseases. I believe that it is in the public interest, in the interest of preserving the health of this country, that these things should be provided and should be required, and they should not supply just one of them.

In the case of iron, again I agree with the figure proposed by Dr. Nelson, that a minimum of 6.15 milligrams per pound of flour, and here I also agree with Dr. Nelson in the maximum which he proposed of four times the minimum.

My reason for increasing the maximum in this instance

is because of the natural iron content of wheat, as I indicated before. It is my opinion that these levels, one should be able to reach these levels in a variety of ways. We should not set any standard which will interfere with the production of a lightly milled flour, or any attempt to obtain these figures from natural wheat sources, and because of the naturally higher iron content of this I feel that there is real reason for having a maximum figure of four times the minimum in the case of iron.

1639 For calcium, I would propose a minimum figure again in agreement with the proposal of Dr. E. M. Nelson, of 492 milligrams per pound of flour. Here again I also am in agreement with his proposed maximum figure of four times this minimum allowance, because of flours which now have calcium added to them, for other purposes.

I believe, however, that calcium should be an optional ingredient, and should not be one of the required ingredients for this special flour.

In the case of vitamin D, I also agree with Dr. Nelson's testimony of 100 International units for each 6¼ ounces of flour. However, I feel that this also should be permitted as an optional ingredient and not a required ingredient. That is because of the other means of obtaining vitamin D.

Mr. Strowd: You don't know whether you said whether iron was optional or not?

The Witness: If I didn't, I meant to say that iron should be required.

Then to summarize, it is my opinion that in the public interest we need a special standard for a reinforced flour which should be given a special name. A number of names have been proposed, and this flour in the public interest should be required to carry thiamin, nicotinic acid, and iron, at the present time; and as soon as reasonably
1640 and practicable, it should also be required to carry riboflavin. It should have as optional ingredients at the present time riboflavin, calcium, vitamin D. I would also include phosphorus as an optional ingredient, the minimum amount of 492 milligrams per pound with a maximum of four times that figure.

The thiamin minimum of 550, and a maximum of 775 International units, and Riboflavin, a minimum of 1.22 milligrams and a maximum of 1.83 milligrams, and nicotinic acid, a minimum of 6.15 milligrams and a maximum

of 10 milligrams; iron, a minimum of 6.15 milligrams, and a maximum of 24.6 milligrams; calcium, a minimum of 492 milligrams, and a maximum of four times that figure; per pound for flour.

Mr. Goodrich: Is that all that you have?

The Witness: Yes.

Cross-Examination by Mr. Goodrich.

Q. In your original testimony, you stated that there were approximately 30 or 40 per cent of the population of the United States now suffering from diet deficiencies.

I would like to have you give us some more information on that, if you will. Is that the total of all diet deficiency diseases, and which is the most prevalent and just such information as you have on that subject.

1641 A. I believe that I said that the dietary surveys indicated that that proportion of the population was receiving an inadequate diet and those figures are based on the surveys of Dr. Stebling and her associates of the Department of Agriculture, and some of them are published in the 1939 Yearbook of the Department of Agriculture. That is indicating that 30 per cent or more of the population receives an inadequate diet.

Q. What is the prevalence of vitamin B-1 deficiency, thiamin deficiency?

A. I can't cite you any definite figures, because there are no definite figures available on the prevalence of thiamin deficiency in this country.

From my clinical experience, and from conversations with other physicians in this country who have had a wide clinical experience, and review of the literature, it is my opinion that mild degrees of thiamin deficiency are very prevalent, and very extensively prevalent.

Q. And can you give us the same type of information with respect to riboflavin deficiency, and nicotinic acid deficiency?

A. In regard to both nicotinic acid and riboflavin deficiency, again there are no statities available on the prevalence of these diseases; such data is not collected.

We have been able to make estimates of the prev-
1642 alence of endemic pellagra in the southern part of the United States in past years, and it has been my opinion that we have not less than 200,000 cases of pellagra or nicotinic acid deficiency in the United States every year.

If we take the whole of the United States, and the various minor degrees of nicotinic acid deficiency, I think the figure would be considerably higher than that.

In the case of riboflavin it is too newly recognized as a clinical entity for us to make any definite estimates. However, again, from my experience in clinics, and from conversations with other clinicians, it is my opinion that riboflavin is probably just as prevalent as pellagra, and again I would call attention to the fact that these three diseases; that is, thiamin deficiency, nicotinic acid deficiency, and riboflavin deficiency directly occur together, because the diets that are deficient in one item, or one of these vitamins, are likely to be deficient in either or all of the rest, and I should also add, I think, that many of these, or most of these cases occur in low income groups, in which flour is a larger item of the diet, and I believe that this flour enriched as I have proposed would be one of the most valuable things that this country can do to correct these deficiency diseases.

1643 Q. Is it your opinion that a definition and standard of identity for this special flour carrying only vitamin B-1, thiamin, as a required ingredient, would not promote honesty and fair dealing in the interest of consumers, and would not be in the interest of public health?

A. It is. I believe that no special flour should be permitted which does not carry the required ingredients, as I have indicated—that is nicotinic acid, thiamin, and iron, at the present time, and later riboflavin. I think it is essential that we do not permit the sale of a variety of products containing only one of these mentioned ingredients. They should all have the required ingredients, and then the others as optional ingredients.

Q. In your statement to the effect that the standard should be based upon the nutritional value of the flour, without distinction to the extraction, texture, and baking qualities, and so forth, you refer primarily to what is desirable from a nutritional standpoint only, do you not?

A. I didn't get the first part of that.

(Pending question read.)

A. Oh, absolutely. I am thinking of this thing only from the standpoint of the public health, of preventing these deficiency diseases, and these quantities which I have proposed are based solely on that consideration.

Q. If it should appear from the testimony brought out

at this hearing that riboflavin concentrates can be
1644 procured at reasonable figures, you would suggest that as a required ingredient rather than as an optional ingredient.

A. Yes, whenever there is definite assurance that riboflavin in the quantities that it will be needed is available, I think that it should be then required. Such information as I have at the present time is to the effect that there is no such quantity of riboflavin available, either as concentrate or as pure material at this time, and that it will be some time before the capacity of this country to produce the required amount of riboflavin will be made.

Q. Is there a deficiency of phosphorus in the American dietary at this time?

A. I know of no such evidence.

Q. Is there a deficiency of calcium in the American dietary at the present time?

A. There is much clinical information to indicate that degrees of calcium deficiency are also very common.

Q. Do you agree with the testimony of Dr. Wilder, to the effect that the fortification of flour with calcium may eventually lead to a decrease in the consumption of milk, and consequent injury to the public health?

A. I do not see how the addition of calcium to flour would seriously interfere with the consumption of milk, and it is my opinion that the addition of this quan-
1645 tity of calcium which I have recommended to flour would be in the interest of the public health.

Mr. Campbell: I don't believe that Dr. Wilder put it in exactly that way.

Mr. Goodrich: I will be glad to be corrected, if you care to correct me on that.

(Discussion off the record.)

Dr. Wilder: I think that I expressed solicitude on the score of people being tempted to think that they were getting all that they needed from milk if they simply got the calcium, and pointed out that milk has other nutritional qualities for which it is desirable to increase its use, and I don't recall exactly what I said, but that is my opinion. I think that I expressed something like that.

Mr. Goodrich: I don't want to be in the position of misquoting.

The Witness: I odn't believe that there is any essential difference between Dr. Wilder's point of view and my point of view. The addition of calcium to flour should by no

means interfere with the utilization of milk, by the general public. My reason for suggesting calcium as an optional ingredient was that in some instances it would be preferable to try to promote the utilization of calcium from other foods, but we must also face the fact that low
1646 income groups as a rule get little milk, and they do get a good bit of flour, and the addition to flour would tend to increase the calcium consumption in the group to which milk is not available.

By Mr. Goodrich:

Q. Do you agree essentially with the testimony of Dr. Wilder that there is no satisfactory evidence that he has seen, of vitamin D deficiency in adults?

A. That is true; I am not an expert in that field; in my clinical experience I have not seen any cases of vitamin D deficiency in adults.

Q. It is for that reason that you recommend vitamin D as an optional ingredient rather than a required ingredient?

A. Yes.

Q. Can you state for the record anything with respect to vitamin B-1, thiamin, or riboflavin concentrate, of what is the meaning of concentrate? What is understood by concentrate in the field of nutrition, and whether or not a concentrate as you understand it differs from a concentrated form of these vitamins in a wheat germ, processed wheat germ or a yeast or something of that kind?

A. I can only give you my personal interpretation of those words.

Q. What do you understand by a vitamin concentrate?

1647 A. Well, to me, in this sense: I assume that you are speaking of vitamin concentrates here as concentrates suitable for the addition to flour, as a means of increasing the vitamin content of that flour.

Q. I have in mind a general question. Is there an understanding among nutritionists of a concentrate as something separate and apart from a concentrated form of vitamin, a concentrated source of vitamin?

A. Well, there is a distinction in my mind.

Q. Can you spell that out a little bit more for the record, please, sir?

A. A vitamin concentrate of a type which would be suitable for addition to flour would have to be in a material

containing a sufficient amount of the vitamin in a small enough volume so that significant amounts of the vitamin could be added to the flour without materially altering the character of the flour.

Q. Can that degree of concentration be obtained in processed wheat germ, or in yeast?

A. To meet these levels, I have proposed?

Q. Yes.

A. No.

Q. It can not be?

A. No.

Mr. Goodrich: I think that that is all, unless you
1648 have something else to add.

The Witness: Let me add just one more statement.

I don't believe anything that I have said in this last statement should be interpreted as indicating, or suggesting, any restriction on the manner in which a flour can be brought to the minimum levels which I have proposed. I feel that the greatest latitude should be permitted in arriving at these minimum quantities.

In milling processes, in the addition of concentrates, i. the addition of pure synthetic materials, they also should be available to the manufacturer of the product, just so that he has a final concentration in his flour which is in conformity with these minimum suggested amounts.

By Mr. Goodrich:

Q. My question was directed primarily to an attempt to bring out the meaning of a vitamin concentrate. There is some testimony in the record already with respect to certain vitamin concentrates, and also with respect to yeast, and wheat germ, as a concentrated form of vitamin B-1, and I was attempting to elicit such information as is available, and as will aid us in defining a riboflavin concentrate, should those be permitted in the standard of identity.

A. My personal feeling is that if a manufacturer
1649 of flour wants to reach to these levels, or attempt to reach these levels by adding wheat germ, or by adding yeast, let him add it.

You asked me for my interpretation of concentrate and I gave it to you, but in doing that, he will so materially change the appearance of the flour that the product might be difficult to dispose of and I think perhaps you saw that in some of the breads that were presented here yesterday.

Mr. Goodrich: I think that that is all. Thank you very much.

Presiding Officer Willcox: Are there any other questions of Dr. Sebrell?

I would like to ask you to clear up one or two points, if you will, Doctor, in connection with the thiamin proposals that you have, the figures of 550 and 775, I think. 50 per cent is 825. I wondered if that was intentional.

The Witness: I think that is 50 per cent, 775. I meant 50 per cent; that is right, 825.

Presiding Officer Willcox: I have a few more questions to ask.

In specifying these minima, you don't object, I assume, to the presence of lesser amounts in the case of the optional ingredients, lesser amounts than the minima specified,
1650 if they are not declared as elements?

I take it that an addition from a mill stream of thiamin might carry with it a certain amount of riboflavin, for instance, but not enough to meet your minimum, and I take it that you would have no objection to that if it was not claimed as containing riboflavin?

The Witness: That is correct. I was thinking of the claims to be made for this product, and I would have no objection to the product containing quantities less than these minima, as long as no claim or representation is made on the basis of such content.

Presiding Officer Willcox: And your recommendation, as an optional ingredient, is for the purpose of permitting it to come in with other things that are desirable, is that correct?

The Witness: That is correct.

Cross-Examination by Dr. Strowd.

Q. Now—

Dr. Wilder: Mr. Presiding Officer, Dr. Strowd permits me to comment, if you will permit, that I made the same mistake in my mathematics. I suggested an increase of 50 per cent and called it 775.

Presiding Officer Willcox: You intended 50 per cent?

Dr. Wilder: Yes, and that related to the 825.

1651 By Dr. Strowd:

Q. Striebling and her associates in circular 507, I believe it is, suggested a daily allowance of one gram of

calcium and 132, which is somewhat higher in both cases than the Food and Drug minimum. Do you agree with that?

A. Do I agree with it as what?

Q. As suggested daily allowance.

A. As a suggest minimum daily allowance?

Q. No, the suggested daily allowance which will include some excess, you know, rather than an absolute minimum.

A. Yes, that is all right. I would have no objection. I agree with that figure. I don't quite see what that has got to do with flour.

Cross-Examination by Dr. Lee.

Q. Dr. Sebrell, did I understand you to say that it is not possible to get enough vitamin B from yeast to put in flour without injuring the flour or the color, or were you referring to riboflavin at that time?

A. He asked me specifically if I thought—your question was a specific one about yeast or wheat germ, and I expressed, I believe, the opinion that in order to reach this minimum thiamin requirement, or riboflavin, or nicotinic acid requirement solely by the addition of yeast
1652 to flour, that you would change the characteristics of the flour.

Q. That is what I thought I understood. Are you aware that there is a dry yeast with over 200 units per gram, and that two grams of this could be added to the flour without spoiling the color of the flour?

A. I am familiar with your high vitamin yeast, and recognize the addition of the yeast to the flour for bread making, but may I ask you a question? Would you recommend the sale of flour in bags, say, six or twelve pound bags of flour, in which the thiamin content was reached by the addition of this yeast?

Q. Not the fresh yeast, but there is a dry yeast that we have with 200 units per gram, and it could be used for that purpose.

A. Well, now, I haven't seen any flour fortified that way, and I would have to say that with that product I don't know what the effect would be on the flour.

Q. I just wanted to bring that out in the record.

Presiding Officer Willcox: Dr. Sebrell, we have been considering these proposed additions from the point of

view of either the optional ingredients or a separate standard, and I wanted to get that clear in the record, whether your objection to the use of one or two of the ingredients
1653 which you think should be required, without the use of all of them, would be objectionable regardless of whether it is treated as a separate identity or optional ingredient.

Perhaps I haven't made that very clear, but you spoke of objecting to the use of some, but not all, of these ingredients in a special flour. Would you object for instance to the authorization of a flour not sole under that special name, but labeled flour with thiamin added?

The Witness: No, as long as it is clear that that flour does not comply with the standard for this name, and they would not be permitted to use the name which will be selected for this special standard, but if they want to sell flour with thiamin and label it as flour with thiamin, and not use this special name, I would have no objection.

Presiding Officer Willcox: Are there other questions?

Cross-Examination by Mr. Thomas.

Q. I would like to ask a question, whether you consider a fair tolerance in the assay of nicotinic acid content, and also in riboflavin—I might put that question because we have got some very practical problems here, in assuring that these minimum and maximums are in the flour.

How are we going to know that they are in the flour between those limits?

1654 A. I believe that this 50 per cent tolerance which I proposed is a fair tolerance.

Q. Our experience in making assays and trying to control it, show that the variable is much more than 50 per cent at the present time, with the present technique of the methods employed, and if the variable in making the tests is more than your minimum and maximum, for policing purposes it seems to me that we are in a bad position.

A. I didn't propose these for policing purposes. I indicated that I think that I proposed these levels purely from the consideration of public health, and consumer interest, and the problem of policing the product is another problem, I believe.

Cross-Examination by Dr. Wilder.

Q. Dr. Sebrell, isn't it a practice of government inspectors, and inspectors generally, to allow tolerances that depend in their degrees of variation or in their accuracy, depending on the facilities available for analyses?

A. You would have to ask someone on the Food and Drug Administration about that. That is beyond my province.

Q. It would seem to me only reasonable that when the possibilities for variations are large, that tolerances
1655 should be proportionately large, and when it is possible to define things acurately, the tolerances should be narrow.

A. I agree with that in principle.

Mr. Goodrich: I think Dr. Sebrell has an appointment at 12:30, and I have one question, on this addition of single vitamins to flour, flour with thiamin added, I believe you said.

You would not consider that to be in the interest of public health, unless there was also a flour on the market with the several required ingredients which you have suggested, would you?

The Witness: I would not consider such a flour to be in the interest of public health, unless this other special standard flour was also available.

Mr. Goodrich: I think that that is all.

Cross-Examination by Mr. Campbell.

Q. Not standard flour; you don't mean standard flour. You meant standard of flour.

A. Yes, I meant this special standard of flour.

Cross-Examination by Mr. Hardenbergh.

Q. Is there any chemical way of determining the amount of nicotinic acid in flour?

1656 A. That again is a policing problem, for the Food and Drug Administration, and the figures that I have proposed are based solely on public health considerations, and I have not considered the difficulties of determination and policing.

Presiding Officer Willcox: Thank you very much.

Cross-Examination by Mr. Sherwood.

Q. I would like to ask one question, Dr. Sebrell, if the process of manufacturing some of these products unavoidably results in providing more than your maximum limit of B-1, or B-2, or nicotinic acid, you wouldn't see any objection on that on nutritional grounds?

A. No. I feel in general that we should have latitude here. My objection in proposing the maximum figures was to prevent unreasonable additions, for the purpose of one manufacturer claiming that my product has got three times the required amount, or what have you.

I see no objection to having more than the maximum in there, if no claims are made on the basis of the quantity there, beyond this required level.

Mr. Sherwood: I see.

Presiding Officer Willcox: I think that that will be all. Thank you very much.

(Witness excused.)

1657 Presiding Officer Willcox: I think that we might adjourn now for lunch. We will meet at two o'clock.

(Whereupon, at 12:30 o'clock p. m., the hearing was recessed until 2 o'clock p. m. the same day.)

1658 Afternoon Session.

(The hearing was resumed at 2:00 o'clock p. m.)

Presiding Officer Willcox: Are you ready to proceed?

Mr. Campbell: Yes. I would like to call Dr. Jolliffe.

Whereupon DR. NORMAN JOLLIFFE was called as a witness for and on behalf of the Millers National Federation, and having been first duly sworn, was examined and testified as follows:

Direct Examination by Mr. Campbell.

Q. Please state your name, residence and profession.

A. Dr. Norman Jolliffe, 22 East 36th Street, New York City. I am a graduate of the University and Bellview Hospital Medical College in 1926. I have been instructor in physiology. I am now Associate Professor of Medicine at New York University College of Medicine and Director

of the Medical Service of the Psychiatric Division at Bellview Hospital, and Director of the Carnegie Corporation Fund for the Study of the Effects of Alcohol on the Individual.

I am a member of the County, State and National American Medical Association, the Academy of Medicine
1659 of New York City, Harvard Society, American Society of Physiology, the Society of Clinical Investigation, Society of Experimental Biology in Medicine.

I think that that is about all.

Q. Have you been especially interested in a study of vitamins in connection with nutrition?

A. Since 1932 my work has been almost exclusively with nutritional problems, particularly as it concerns the vitamins.

Q. Have you made contributions to the literature on that subject that have been published in various publications?

A. I have made numerous publications appearing in the Journal of the American Medical Association, the Journal of Clinical Investigation, the Journal of the American Dietetic Association, Journal of Biological Chemistry, Annals of Internal Medicine, International Medical Clinics of North America, and several others.

Q. Now, Doctor, in this proceeding, we have been discussing the question of the addition of vitamins and minerals to flour. Will you please discuss or make any statement that you would care to make, on that question, from the standpoint of nutrition and the interest of the public?

A. There now exists in the American diet, as shown by numerous studies, particularly those of Stiebling
1660 and associates, and Tisdal, and from our own clinical experience in seeing these individuals, a substantial deficiency of the vitamins, especially of the B complex and more particularly of Vitamins and also of iron. This deficiency has been contributed to by the declining use of flour products the declining vitamin and mineral content of these flours, and lastly, I believe, by the tremendous increase in the consumption of sugar.

A substantial addition of Vitamins to flour, and particularly of iron, in the list of minerals, would contribute to the general welfare of our entire population, and it would contribute particularly to the welfare of the poorer section of our population, who probably eat more of the bread products than the more affluent members. For this

reason, and in the interest of general public health, and nutrition, I have strongly advocated for some time the addition of certain of the vitamins and certain of the minerals to our staple flour.

Specifically, I would add, specifically, the ingredients that should be added would be iron, nicotinic acid, and thiamin hydro-chloride. I believe that nutritionally ribo-flavin is essential, that that be added, but I realize the procurement difficulties, and for that reason would allow a reasonable period of time for those procurement difficulties to be overcome.

1661 I would say that Vitamin D, and calcium, should be optional ingredients, Vitamins A and C do not seem to me to—or let us put it this way, that flour does not seem to me to be a satisfactory carrier for either Vitamin A or Vitamin C, and as for phosphorus I have no objection to that being put in, as long as no particular claims should be made as to its nutritional desirability.

As to the amount of iron, I am in essential agreement with Dr. Sebrell, and Dr. Wilder, and Dr. Nelson, that the minimum level should be approximately 6.15 milligrams per pound of flour, that the upper limits should be approximately four times this, or 24.6 milligrams per pound of flour.

Nicotinic acid I believe should be placed in at approximately 6.15 level per pound of flour, with a maximum ceiling of a plus 50 per cent, or approximately 10 milligrams.

That thiamin hydrochloride, or Vitamin B_1 should be in flour to a minimum of 550 international units per pound, allowing again a coverage of 50 per cent, making the upper level approximately 825 international units per pound. These figures that I have given are in essential agreement with the previous testimony given this morning.

I have no difference of opinion as to the testimony this morning concerning Vitamin D as an optional in-
1662 levels of approximately 400 units per pound of flour, with calcium of approximately 492 milligrams per pound, with upper limit of four times that amount.

By Mr. Campbell:

Q. Doctor, would you develop a little more in detail the Vitamin B_1, the thiamin deficiency, and with respect to the reasons which prompt you to suggest a minimum level for that of 550 international units per pound of flour?

A. This level I have arrived at from several considerations, the first one being that if we give to flour less than

530 international units per pound, we would not be supplying the American public, and it would not be for their interest, it would not be for the interest of good nutrition of the consumer, particularly the lower third economically of our population, to have less than this amount in there. It may be that I should develop that a little bit further, and state some reasons for the disagreement on daily requirements of Vitamin B_1. I think for that I should explain that there are, or that the nervous system may be divided for the purposes of at least Vitamin B_1 requirements, into three parts: First, the very old nervous system, the part that was laid down in the beginning, the part that is present in the lower animals, the part that is generally included in the basal ganglion region.

1663 Now, that portion of the nervous system requires very, very little thiamin hydrochloride to keep functioning.

Then there is a part of the nervous system that is developed in a middle region, let us say, that part includes among others the peripheral nerves, and it is on that part of the nervous system that requires substantially more thiamin hydrochloride to kep in perfect health than the very oldest or the basal ganglion.

Now, it is on the maintenance of these parts of the nervous system that the determination of 250 units or thereabouts as being a minimum requirement for the human being has been made. These individuals have forgotten, or have not paid attention to the fact that we have in man, and in human beings, a cortext, a part that is much more highly developed than we have in our white rat, that these things have been tested on, that requires a substantially higher level of thiamin chloride than the peripheral nervous system. The amount that is required for the adequate nutrition and to maintain in adequate health, the cortex of the brain, is much higher than 250 units, and more nearly approaches 450 international units for a man of approximately 70 kilograms, and that at rest.

Now, most of us are not at rest, at least loafing around in a room, and have nothing to do except eat three meals that are supplied to us by dieticians.

1664 Also, there is a substantial fraction of our population that weighs more than 70 kilograms, or about 154 pounds, and so in the interest of public health, and nutrition, we have to take into consideration not the aver-

age individual, but the individual that weighs 200 pounds, and to supply him only with the amount that would supply a 70 kilogram man is certainly not in the interest of public health, and nutrition, and is not satisfactory. For that reason, the reason that a large fraction of our poulation, many people that are working, weigh much more than 156 pounds, and also that since they are working, their total metabolism has increased, I would say that the best level that should be aimed at, and should be reached for adequate nutrition, for maintaining our people in not just bare existence, but for abundant health, should be around 900 International units daily, of thiamin chloride, and it is on that basis that I have suggested 550 international units as the minimum per pound of flour.

By Mr. Campbell:

Q. On what basis, if you know, was the 250 units of B_1 per day set by the League of Nations?

A. I was not on that committee, but as I recall it, that is the amount that will prevent the development of peripheral neuritis. Actually that amount will not prevent the development of peripheral neuritis, if the individual
1665 happens to weigh much more than 50 or 60 kilograms, it will not even prevent that, let alone the development of proper cardial function.

Q. Have you confirmed Dr. Wilder's observation on experimental subjects as to the Minimum B_1 in take?

A. Yes, those observations of Dr. Wilder, on his experimental subjects, agree in all essential details with our findings on four individuals, with this exception:

That our individuals developed signs and symptoms of B_1 deficiency much earlier than did his individuals due to the fact that he kept his individuals at rest, in a room, while our individuals were four resident physicians who had to work like the devil, and that increased or shortened very decidedly the period of time in which they developed these signs that Dr. Wilder has described.

Q. Doctor, could you tell us what the average daily intake of calories is?

A. The figures given vary. It is probably somewhere between 2,500 and 3,000 calories. I am told that the experience of our Army shows that they eat about 4,500 calories, that is, soldiers, which is probably more nearly

the amount that people engaged in physical occupations eat, particularly the man.

Q. To what extent does sugar play a part in the production of deficiency diseases?

1666 A. I think it plays a very important part in the development of deficiency diseases. Sugar is, for practical purposes, vitamin and mineral-free. We knew that many years ago, particularly in colonial times, that the average per capita consumption of sugar was probably around five pounds per capita, or about 25 calories per day. It is now around 112 pounds per capita per year, somewhere around 600 or 700 calories per day. I have not figured that out but that is approximately what it is.

With this tremendous increase in the consumption of sugar, which is Vitamin free, that also adds to the necessity for having in other articles of food, a very adequate source of the essential elements of nutrition.

Q. Is there anything further that you would like to say on this subject?

A. I don't believe so.

Mr. Campbell: I think that that is all.

Presiding Officer Willcox: Mr. Goodrich.

Mr. Goodrich: It will take me just a minute. If anyone cares to go ahead they can go right on with the examination.

Presiding Officer Willcox: Are there other questions of Dr. Jolliffe?

Dr. Williams: I would like to ask whether Dr. Jolliffe makes any distinction in his mind between sugar and
1667 other forms of carbohydrate from the standpoint of vitamin requirements?

The Witness: No.

Presiding Officer Willcox: Do you know anything, Dr. Jolliffe, as to the means of assaying any of these nutritive factors that you have spoken of? The question was raised this morning, of the difficulty of keeping products within these limits.

The Witness: I am not an expert on that field at all. I know that it is extremely difficult.

Mr. Thomas: Do you differentiate between synthetic vitamins and natural vitamins?

The Witness: I would not differentiate and do not differentiate between synthetic and the natural vitamins.

Mr. Thode: That maximum figure that you named is

really an empirical figure that should not be limited for purposes of control, should it? There should be a little overage because of the difficulties of assays, and so forth?

The Witness: I think that certainly there has to be tolerance allowed for all of those figures.

Cross-Examination by Mr. Goodrich.

Q. Your suggestion was that staple flour was a
1668 proper vehicle for the addition of these several vitamins and mineral products; is it your idea that there be a separate flour fortified with all of these items, to be a separate product from flour now on the market?

A. It is my idea that a flour labeled, distinctively labeled, as a vitaminized flour, using that as an illustration, should contain, and sold under that label, should contain at least nicotinic acid, thiamin, and iron, in the amounts stated.

Q. Do you have an opinion which you would care to express with respect to vitamin and mineral supplementation to any other type of flour, say self-rising flour, or something of that kind? I am just trying to develop your idea on staple flour, as a proper vehicle?

A. I see no reason why it should not be added to those, that is, nutritionally speaking.

Q. You have stated in answer to a question by Mr. Thode, that this figure which you had set for Vitamin B, was more or less an empirical figure, or at least he stated it, and I don't know whether you answered it for him or not.

A. I did not state that as an empirical figure. I think if you fall below that you are going to get into trouble.

Mr. Thode: I said the maximum.

1669 The Witness: The maximum was empirical, but the minimum was not.

By Mr. Goodrich:

Q Now, on your figures for thiamin hydrochloride requirements, are your figures substantially higher than the recognized daily requirement today?

Mr. Campbell: Wait a minute, before you answer that. What do you mean by the record? The record in this proceeding?

Mr. Goodrich: I am talking about among nutritionists.

The Witness: That would depend on what basis they measure their requirements; if they have measured their requirements on the prevention of periphral neuritis, an old part of the nervous system that requires much less, of course they are approximately correct, and even as to that I think that they are a little low but for the cortex, and the more civilized functions of human beings, they require very much higher than they have indicated. You see when they test those out on rats and things, they don't have this part.

Q. Well, now, let us pursue that a little bit. The thiamin hydrochloride is an aid in the metabolism of the plant or animal?

A. Yes.

1670 Q. And the energy requirements by the cortex is nervous energy, is it not?

A. I don't know what you mean by nervous energy. It requires energy just the same as—

Q. The nervous system rather than physical?

A. It is the same energy.

Q. There is some controversy about that, isn't there?

A. I don't think so, only among lay people.

Q. Is there any material available which you could refer us to in the record, for what portion of the energy is used in mental operations, and what proportion in physical operations, what proportion is used by the cortex, or anything of that sort, and what its proportional requirement is and what the proportional requirement is of the others?

A. There are figures available. They are very recent figures for the per gram energy requirements of certain portions of the brain. I have read those over, but I could not give you the figures. It is essentially higher than muscle, if that is what you mean; it is essentially higher than muscle, and approaches such a very active—or I believe it is even higher than certain extremely active tissues such as the kidney; it is continually working.

Q. The requirement for the brain?

1671 A. Yes, and it also shows that the requirement for nervous tissue is decidedly different in different portions of the nervous system. If you take out an oblongatal that is the very old portion, where the basal neurone are located, it is distinctly lower than if you take it from the cortex of the brain, where the most civilized functions are located.

Q. A considerable amount of literature exists with respect to the requirement of B_1, does it not?

A. Yes.

Q. People such as Dr. Cowgill, and a number of others, have worked on this subject?

A. Yes.

Q. Do they place the B_1 requirement as high as you have?

A. They have not placed the B_1 requirements as high as I have but only because they did not include the functions of the cortex, but the functions, in other words, they made it on the amount that would just prevent the development of beriberi.

Q. And their figures range from about 135 international units, to about 450 international units, is that right?

A. Yes. I don't recall, but if you say so, I will accept the figures.

Q. Remember I am a lay person. That is essen-
1672 tially true, I take it?

A. Yes, that is essentially true.

Q. In speaking of the additional requirements for a heavier and more active man than a 70 kilogram man at rest, we have to also consider in this the differences in the probable diet, or consumption, daily consumption of food, and calorie in-take of a man so engaged, and a man at rest, and of less weight?

A. Yes.

Q. And that would account for some of the differences?

A. That would accentuate the differences rather than minimize them, because an individual—

Q. That is assuming that the diet was void of all vitamins and minerals.

A. Would you restate that again?

Mr. Goodrich: I will have him read it.

(The pending question was read by the reporter.)

The Witness: If a diet under those conditions was void of all vitamins and minerals, and say a 70 kilogram man would take 3,000 calories, and a 90 kilogram man would take 4,500 calories, then the increase would not only be proportional to his increase in weight, which it is proportional to, but it would also be proportional to his increase
in calories, so that it would not be just the mere fact
1673 it is not arithmetical, but geometric, I will put it that way, the increase is much more rapid because of his increased caloric in-take.

Mr. Campbell: The requirement of B_1 would increase?

The Witness: Yes.

Presiding Officer Willcox: Do you mean that the ratio of B_1 to calories should be higher in a heavier man than that ratio would be in a lighter man?

The Witness: There is pretty good evidence showing that an individual who weighs decidedly more than a smaller individual, let us say, requires an increased ratio over that smaller individual, in addition to requiring an increased amount, because of his increased food consumption.

By Mr. Goodrich:

Q. With an increase of food consumption, you are likely to have a better in-take of vitamins and minerals?

A. That is to my mind very questionable, because the individuals that have a very high food in-take, as a rule their consumption of vegetables and meats and things, particularly in our poorer population, is governed by their pocketbook, and they get their increased calories from the very cheapest sources, such as from flour and its products, and from sugar, and so here again you are accentuating the differences.

1674. Q. You don't explain these diet deficiencies in the low income groups in their inability to buy enough food to supply their caloric needs, but on the basis of the things that they buy not supplying the essential vitamins?

A. I think that that is a fair statement. They can not; their pocketbook demands that they buy the cheaper sources of calories.

Q. You base part of your testimony with respect to Vitamin B_1 requirements upon experiments which you referred to but which you did not explain in any great detail, upon these four doctors. I wonder if you could explain that a little bit?

A. These four doctors were placed on the diet of approximately that given by Dr. Wilder to his six subjects. The difference was that they were not required to remain in the ward, but conducted their actual work, their daily routine work, and instead of symptoms developing thirty or sixty days later because of their increased metabolic activity, they developed symptoms within ten days, and again our subjects were also larger than Dr. Wilder's subjects, being people of more or less my size, except one who was about 50 or 55 kilograms, and he went along for a month, without developing symptoms, while the large individuals, running around 80 to 90 kilograms, developed these signs and symptoms within ten days.

1675 Mr. Goodrich: I think that that is all. Thank you.

Presiding Officer Willcox: Are there any further questions?

(No response.)

(Witness excused.)

Mr. Campbell: Dr. Williams said he wanted to go on and make a statement for himself.

Presiding Officer Willcox: Dr. Williams, you want to make a statement?

Dr. Williams: Yes.

Whereupon DR. ROBERT R. WILLIAMS, was called as a witness for and on behalf of Other Parties and having been first duly sworn, was examined and testified as follows:

Direct Examination.

Presiding Officer Willcox: State your name and occupation and residence for the record, please.

The Witness: My name is Robert R. Williams, 297 Summit Avenue, Summit, New Jersey. I am Chemical Director for the Bell Telephone Laboratories at 463 Wells Street, New York City. My interest in this matter has nothing to do with my connection with the Bell Telephone Laboratories.

I began the study of vitamins in the Philippines in 1676 1910, and that was a little more than a year before the term "vitamin" was invented, and I have been engaged continuously in the vitamin study since that time, centering very largely around thiamin, or as we used to call it when we first began to work, the beriberi preventative substance.

During the first ten years of this work, it was one of my major responsibilities in connection with my employment, first with the Philippine Government and later with the Bureau of Chemistry, of the Department of Agriculture, here in Washington, in which connection, incidentally, I was for a time associated with the Food and Drug enforcement work, for the last twenty years it has been an avocational undertaking, done very largely on weekends and holidays, and evenings, and with the aid of financial support drawn from many sources, largely from organizations of

the type of the Carnegie Corporation, and other foundations supplying funds for scientific research.

Inasmuch as my undertaking in this regard was avocational and was in the interest of science rather than with any commercial motive, I never counted on any recompense for the work that I did, and indeed I spent many thousands of dollars of my own money in supporting the job from time to time, when funds from these foundation sources ran out, so in accordance with that idea and
1677 history, when in 1933 to 1936 my associates and I were able to work out the constitution of the beriberi vitamin or thiamin as it is now called, and to develop a commercial method for the synthesis of this substance, our entire group assigned all of the patents connected with the isolation and the synthesis of thiamin to Research Corporation, a non-profit organization, whose principal offices are in New York, 405 Lexington Avenue, and this organization, Research Corporation, was founded some twenty odd years ago for the purpose of exploiting patents which might be assigned to it by inventors who felt that they had a social or public obligation to have their patents administered in the public interest, rather than for private gain.

Its Board of Directors includes many eminent men. I might mention Dr. Compton, President of the Massachusetts Institute of Technology, Dr. Bowman, President of Johns Hopkins University, Dr. Bush, President of the Carnegie Institution, and other men of similar representative character. All of the profits which come to Research Corporation from the administration of patents are used in the support of scientific research or other public objects of a kindred nature, and in harmony with that general plan the patents concerned with thiamin are being administered in a similar fashion, with the exception that a special fund to which 50 per cent of all of the proceeds is now devoted, called the Williams-Waterman Fund
1678 for the Combat of Dietary Disease has been set up.

The object, as the title of this fund would suggest, is to promote experimental work, educational work, and other measures which may be deemed desirable for the eradication of diseases due to nutritional deficiencies.

Last year I paid a visit to Europe, and interviewed many of the leading nutritionists of Continental Europe as well as England, with regard to this problem of the utilization

of vitamins for the eradication of diseases, particularly with reference to thiamin, and particularly with reference to the problem of the grains which are decorticated; in the Orient it is rice; in the western world, it is wheat.

I talked at length with Professor Jansen, who was the man who originally isolated Vitamin B, from rice polish, working in Java, in 1926, and he laid plans, sadly disturbed by the events since, for introducing at a proper time a supply of thiamin into the diet of the people of the Dutch East Indies.

I also have correspondents in the Philippines and in British India, with regard to the same product. There the problem is quite a different one from the problem here because no feasible way of putting the vitamins on the grain has been devised so that it will not be washed off in the preparation of the rice for cooking, and other measures must be taken than those that are feasible here.

During the course of my European visit, I also talked to Professor Drummond, and Professor Todd of Manchester, and particularly Sir Henry Dale of the Medical Research Council, about this very problem, and can report that a year ago last April and May these gentlemen were all well aware of the nutritional problems existing in England at that time, and saw no obstacle other than the price of the vitamin to the introduction of the substance into flour, a forecast of the event which has taken place more recently, of the decision of the British Government to require the addition of thiamin to flour.

My visit also took me to Scandinavia, where I encountered a great deal of further evidence of the recognition of a shortage in diet of that area of the world, due to the extensive use of white flour, particularly emphasis was laid upon the clinical observation in that area, with regard to the occurrence of various neuritis and rheumatism, which was associated by many of the clinicians of Stockholm with a deficiency of thiamin.

In my opinion, the time has now come when we must face the problem of utilizing the synthetic vitamins in an effective way for the mass eradication of deficiency diseases, rather than for treatment as the disease appears.

It is my opinion that honesty and fair dealing in the marketing of foodstuffs and in the interest of the consumer require that we observe a few simple principles in making decisions as to what foods should be forti-

fied, and with what vitamins or minerals they should be fortified, and the amounts which are appropriate.

In the first place, it seems to me that we should limit additions of vitamins at the outset, to staple foods, or limit our concern about the problem to staple foods, because those are the foods that count most heavily with regard to establishing a general deficiency level.

We need to consider, in choosing which vitamins shall be added to a particular staple food, which are compatible and feasible from general commercial and manufacturing standpoints. We should sanction amounts which are appropriate to the metabolism of the food with which we are concerned, not greatly more than what is appropriate for the metabolism of the food for which we are concerned, because that will have the tendency to converting our foods into medicines, and emphasizing in the public mind the thought which I believe does a great deal of harm at present, that one can by taking an occasional dish of this or that product protect himself against a deficiency of any particular vitamin.

Many people have the idea that an orange once in a while,
insures that you can't be deficient in Vitamin C, for
1681 example. We should not add much more than the
amount required for proper metabolism of the food, for the reasons that I have indicated, and we should not, in my opinion, in the public interest, add much less than the proper amount, because that would encourage the playing up in advertising of relatively insignificant additions, which could not make a major difference in the nutrition of people but might lead the people to believe that they were protecting themselves when they actually were not.

Also, I feel that this consideration is important, that the burden of making good the deficiency in the diet which is contributed by a particular kind of food ought to be supported by the industry that is marketing that food, that is, rather than to thrust upon some other industries the responsibility of making good its own deficiencies.

And then perhaps above all, we have to pay regard to the matter of cost in fortifying these foods with regard to the constituents that they lack for proper nutrition. Obviously the poor of each country, and particularly of the United States, because that is what we are concerned with here today, who suffer most in general from Vitamin deficiencies, the moment one adopts a scheme for handling

a staple food which adds substantially to its cost, one tends thereby to limit the consumption of that improved
1682 form of foods to the upper classes of the population, and to take it out of the hands of the lower classes of the population.

Now, in approaching the problem of what specific vitamins should in the public interest be put into flour at the present time, my own evidence comes from somewhat different sources than that of the medical gentlemen whom we have heard testify today. They have dealt in their own experience with human subjects, and my own qualifications are those of a chemist, who has dealt a great deal with the experiments in nutrition, with animals, and as some of the testimony has pointed out, one can not always draw final conclusions from animal experiments with regard to human needs.

I can, however, confirm the testimony of Dr. Wilder and Dr. Jolliffe, and Dr. Sebrell, with regard to the thiamin situation in an indirect way, and that is this:

That the demand for thiamin has far exceeded the expectations of anyone who was concerned with the study of nutrition or with the development of methods of producing this substance, and that in spite of the fact that Research Corporation has not spent a single dollar for advertising that the licensees have not advertised in lay journals at all, and that even those who have vended the product in retail packages have confined their advertising very
1683 largely to the medical journals, so that at one time not many months ago, it was the case that about 80 per cent of the sales of thiamin at that time were going apparently to channels which were being directed by the medical profession, so that the testimony of Dr. Jolliffe, and Dr. Sebrell and Dr. Wilder indicates not a peculiar or fanatical attitude on their part but an attitude that must be shared very widely by the medical profession of the United States, or this would not be the case.

No person has been more surprised than I by the increasing demand which has grown steadily from the very day that the material was first put upon the market, far beyond anything that was expected. The original idea that we had when we were studying the subject of beriberi in the Philippines was that beriberi was a disease peculiar to the Orient and that you would probably never find beriberi among the population except those living on restricted sort

of diet, but steadily throughout this time the evidence has grown that the deficiency is far more widespread than it was predicted.

Now, judging from animal experiments, judging from a survey, a continuous survey of the medical literature and nutrition literature and judging from extensive conversations with the leading nutritionists of Europe and the United States, I have come to the opinion that the
1684 vitamins which should be added to a flour suitable for general nutritional purposes in the United States should be required to be added, are thiamin and nicotinic acid.

With regard to the amount of thiamin to be added, my recommendation is 1¾ milligrams as a minimum and 2½ milligrams as a maximum per pound.

The lower levels, that is, the minimum level specified, is one which has been included in experimental work of a great many people, using animals. For example, from my own laboratory several years ago, we reported an experiment with rats upon the Gerson spoon diet, a casein starch diet, with in-takes ranging from 5 to 160 micrograins per day per rat, and with every interval the time-growth rate of the animal was increased. That covers a range of up to about four times this minimum.

Now, that sort of an increase, with increasing amounts of thiamin, does not hold for all diets, over that complete range, but it is a rather general property of diets that they are subject to increases over a wide range up to a level higher than that which is commonly available in foodstuffs.

We did the same experiment with animals on a diet composed of two-thirds whole wheat, and one-third whole milk. That diet in its initial state contained about the maximum amount here specified, of 2½ milligrams per
1685 pound of diet, and with that diet it was not possible to demonstrate any added increment of growth with still further increasing amounts of thiamin.

Reference has been made here to the recommendation of the League of Nations with regard to a suitable estimate of the human requirement. I believe that it was mentioned as 250 units. Actually, as I recall, the League of Nations' figure was 300 units, and I would like to point out that that 300 international units specified at that time was based upon the old international unit, which was at that time standard for thiamin. Since that time

the standard has been revised, since the pure thiamin became available so that one unit is now three micrograms of thiamin, but that is only about two-thirds of the amount of thiamin that is actually present in the old international standard ascorbic, so that right there the League of Nations figure has to be revised upward by 50 per cent in order to make it equivalent to what it was stated to be at the time it was written.

Mr. Campbell: Or 450 now?

The Witness: Yes. In addition to that growing evidence, largely from the medical field, of the type that Dr. Jolliffe has emphasized, indicates that the human requirement must be estimated upward rather than downward, or kept on a level with that of the rat. Under
1686 those circumstances, and in view of the evidence that with many diets, increasing amounts of thiamin do improve the nutrition as indicated by rate of growth, I am convinced that it is necessary if we are to really protect the American public in this regard, to adopt a minimum of 1¾ milligram per pound for this especially designated flour, the allowance of a maximum of 2½ milligrams is merely to provide some degree of flexibility, for the manufacturer, so that if he wishes to use one or another form of natural fortifying materials, he can adapt his manufacturing schemes to fit a flexible arrangement far better than he can an inflexible one.

Also, in the case of nicotinic acid, there is the further need, and very important one, in that instance, that the methods of analysis are so crude that considerable latitude must be allowed on that account. In the case of thiamin, the analytical methods are not as good as they might be, but they probably do not in themselves require quite so large a latitude as that.

As to the other vitamins which have been discussed in connection with the treatment of flour in order to improve its nutritional properties, I do not wish to go into so much detail because I do not feel so specially qualified in those fields. I would like, however, to subscribe to the opinion expressed by the other people who have testified
1687 today, to the desirability in the public interest of adding nicotinic acid, because of the wide-spread prevalence of pellagra, in the United States, at a level of 6.15 milligrams per pound, and a maximum of 10 milligrams per pound.

I shall pass over the matter of iron addition entirely.

as I have not made any special study of that subject, and can not add anything to what has been said.

With regard to the addition of vitamins A and C, I am in full agreement with the testimony of Dr. Nelson, that they are sufficiently unstable, under the conditions of the use of flour, so that they would not be wise additions to that commodity.

I also wish to express a doubt in view of the testimony that has been offered here today with regard to the wisdom of including "D" as an optional requirement, primarily for the reason that the more vitamins are added, the more will this special flour cost, and the more tendency there will be to divert it from the hands of the poor who need it most, into the hands of the people who can well afford to be fussy about what they eat.

Now, I have gathered from the testimony of Dr. Jolliffe and Dr. Wilder, as well as Dr. Sebrell, that there is no clearcut evidence of the need of Vitamin D from the standpoint of human nutrition, as obtained from clinical
1688 observation, as far as flour is concerned. My own opinion is, if one is in doubt whether a vitamin should be added to a food product, then don't do it.

Now, as to the optional ingredients which have been mentioned, I am of the opinion that riboflavin should be added to flour, that this addition should be introduced at the present time as optional addition rather than as a required addition, because the best available evidence indicates that the supply of riboflavin at the present time is wholly inadequate to treat any substantial fraction of the flour production.

Also, I would agree that because of the difficulty of analysis of riboflavin, and the desirability of some degree of flexibility in these formulas, that a maximum of 1.83 milligrams per pound should be permitted in the case of riboflavin.

It would seem to me desirable that this flour should receive some form of distinctive name, because an essential part of our problem is that of the education of the public, with regard to the value of this reform, at least it is a reform as I construe it, and if there is a great diversity of products sold under a great diversity of names and with a great diversity of formulas, then the public is going to be merely confused by the changes, and prob-
ably wind up by taking the old-fashioned flour instead
1689 of seeking the product that would actually lead to better nutrition on their part.

I think that that is all that I have to say.

Cross-Examination by Mr. Goodrich.

Q. Dr. Williams, have you through your Williams-Waterman Fund, to Combat Nutritional Diseases or through any other organization, established a program with respect to fortification of foods in general?

You referred to fortification of staple foods, and did not define your terms on that, and I am wondering if you have arrived at some determination on that, and can give that for the record?

A. At the present time the fund is supporting a number of studies bearing upon nutritional disorders, bearing upon the more precise determination of requirements under certain special conditions, and so on. At the present moment, the only experiments that are going on, directed specifically at the problem of just what benefit would accrue from the addition of a moderate amount of thiamin to the American diet, is an experiment which I am just beginning, in my own laboratories, and no results have yet come out of it to report.

We also are considering experiments in orphan asylums or other institutions of that sort, where we can deal
1690 with the growth of children, as affected by their thiamin in-take but that work is yet to be carried through.

Q. Then, in your statement with respect to staple foods, you have decided that flour is a suitable carrier and a suitable place to make your initial step in fortification, and the rest will have to wait until your determinations on the basis of your experiments are forthcoming?

A. Well, we hope that the world won't wait on our determinations, and in fact we know very well that they are not, and I did not mean to overemphasize this particular thing, but to simply point out the reason for my interest in this subject.

It is my opinion that we shall have to consider other staple foods presently, and that sugar is the second one that should receive serious consideration, as far as the United States is concerned, but I also had in mind in mentioning staple foods, the problem of polished rice in beriberi in the Orient, and we hope to undertake some work in that field.

Q. I understand that you probably will not be here during the remainder of the hearing, and there are involved here a number of foods, flour, self-rising flour,

farina, and I believe semolina, and phosphated flour, all of which are suggested that additions be made, and I wondered if your committee, or there is within your
1691 knowledge, any determination which has been made with respect to a general program to be followed in the fortification of foods.

A. The matter of the phosphated and self-rising flours I think represents a problem of very great importance, because of the extensive use of that type of flour in the South, where geographically, probably, these Vitamin B complex deficiencies are most extensive. It would be my own thought that the phosphated and self-rising flour should be included in this same category, that the mere fact that a flour is phosphated, or is provided with a leavening agent, should be no reason why it should not be permitted to come under the definition of this distinctive flour with the same vitamin additions that I have recommended for the flour of the other type.

There is an additional problem with regard to thiamin in such self rising flours as phosphated flours, in that there is a greater loss of thiamin in the baking of biscuits or other self-rising flour mixtures, than in the baking of yeast bread, and that loss will perhaps rise to about 40 per cent, whereas in yeast breads it is nearer 10 per cent or can be held even below that figure, so that it is a more urgent problem for the South, but I don't know enough about it to quite justify setting different standards for
1692 the self-rising and phosphated flours, than prevail for the other flours, and moreover it is my understanding that there is a good deal of soft wheat flour which is sold in the South that is neither phosphated nor self-rising but nevertheless does go into making home-made biscuits, and would be subject to the same sort of loss. We can't obtain perfection in a day, we must take those measures that seem to us at the present time distinctly beneficial to public health, and try to improve still further, in the future, if we can.

Q. In your testimony with respect to the vitamin deficiencies among the lower income groups, is it your opinion as it was Dr. Jolliffe's, that the people in the lower income groups are attaining a satisfactory caloric in-take but not a satisfactory amount of vitamins and minerals, due to their substitution of cereals and some of the cheaper foods; for meats and vegetables?

A. In a general way, that is true, although I feel that

there is an actual deficiency of calories, in addition to that other, in some of the really low income groups. Dr. Stiebling's study did not include the very lowest income groups, and I discussed that at some length with her and ascertained that the population that she sampled was a population representing about the middle 75 per cent of the population, leaving out the upper crust, and the lowest tenth or so of the population, and that lowest
1693 tenth probably suffers a good deal from actually deficient caloric in-take.

Q. And to what do you attribute the increase in deficiency of thiamin in the American dietary?

A. Primarily to the increasing milling of flour, if one looks back over a period of fifty or sixty years, and the increasing use of sugar.

Q. Do you base your recommendations as to 500 to 825 U. S. P. units of thiamin per pound of flour, on the daily requirements of how much—the question is poorly framed, but I think that you understand it?

A. Well, the minimum daily requirement for man in the case of thiamin must be determined, and must be related to some very definite reference standard because of the fact that perhaps more than any other case, in the case of any other vitamin, added amounts show increasing benefits, but with a diminishing return for each additional increment, so that it is possible to keep an animal alive for long periods of time on an amount that is very insufficient and very far insufficient, for the permanent support or maintenance of reproductive function, for example.

On that account, I am inclined to feel that the minimal requirement for thiamin is not the proper standard, that the proper standard is a desirable or satisfactory supply rather than the minimal requirement in any sense that
1694 it can be determined by direct experiment.

Q. Your figures are based upon animal experimentation completed in your own laboratory?

A. Based primarily upon animal experimentation, but I have read the medical literature, and I have been in contact with the experience in the human field, and have been endeavoring for years past to correlate the two, and the evidence is decidedly that the human requirement tends to be higher per calory, than the rat, for anything like abundant health.

Now, of course, in working with animals, you can't ask any questions, and you can't detect subjective symptoms.

and you can't detect minor deficiencies of behavior by biological performance that can be detected oftentimes in human beings, so that my feeling is that putting together the experimental evidence on animals, the determinations of the thiamin levels of populations where beriberi has occasionally occurred, compared with other diets where it has not appeared, plus the clinical evidence of the past few years, with regard to the prevalence of thiamin deficiency among supposedly well-fed populations, I believe that about 900 units daily is required in order to provide vigorous and abundant health for the average human being.

1695 We must take into account, as Dr. Jolliffe pointed out, the bigger man, the individual that is subjected to unusual strains, and after all it seems to me pregnancy is not an abnormal function, or condition, for the human race, and that we ought to provide something for the increased requirement for pregnancy and lactation.

Q. In the flour fed to the general public?

A. Yes.

Q. Have you performed a number of experiments with vitamin B_1 or thiamin hydrochloride, or thiamin, whichever we want to call it, with special reference to the loss in cooking, and so forth? Can you give us any information as to the stability of the vitamin?

A. Only in a rather general way. In the baking of yeast breads it is almost within the experimental error of determination.

Q. That is just the heat in the yeast?

A. The heat in the loaf, yes, which gets up pretty close to the boiling point of water, and there the loss is 5 per cent, or possibly 10 per cent, or something of that sort. In the case of the soda biscuit, because of the more alkaline nature of the mix, it is higher. I should say 40 to 50 per cent is a more typical figure, but of course in preparing biscuits, varying amount of soda are added, and so varying conditions can be attained, and I think the range is much wider than that.

1696 As to other foods, there are very substantial losses that do take place in some instances. Tomatoes apparently can be cooked with almost negligible losses, being fairly acid fruits; on the other hand the roasting of pork results in at least a 50 per cent loss, and pork is of all of the meats, much the richest one.

Cooking losses also occur due to the solubility in water and the common practice of discarding a good deal of water

in which vegetables are cooked. We discard far more than people realize. We either discard it in the kitchen or put it in the serving dish on the table and it is left there when the individual is served, or it is left on the plate itself, so that the amount of cooking waters from vegetables, aside from soups, actually taken into the human mouth, is not a very large proportion.

Q. Can you give for the record, any information regarding the chemical reaction of the thiamin chloride in a solution with other vitamins or with minerals, or mineral adidtions or with potassium bromate which has been suggested as an optional ingredient?

A. There is no serious reaction of thiamin with any other of the vitamins to my knowledge, and it is my opinion that any losses that would arise from potassium bromate additions would be negligible. The addition of alkaline agents tends to be destructive to thiamin.

1697 The sulphuring of foods is extremely destructive to any thiamin present in the food, but in general there are no known incompatibilities of thiamin with other vitamins, or significant minerals.

Q. And have you had experience with thiamin in the presence of ordinary bleaching agents used in flour?

A. I have not.

Q. Is thiamin a stable vitamin in storage?

A. Yes, in the dry state it is quite stable.

Q. It would remain in the flour indefinitely during storage, there would be no possibility of loss?

A. In my opinion, unless there were obvious mold growth or something of that sort, that would be stable.

Q. And thiamin, unlike riboflavin, is stable in spite of light? Light does not affect it at all?

A. No.

Q. And moisture content of the flour, would that have any reaction on it?

A. Except as it might stimulate the growth of the microorganisms, no. If the moisture content is kept down so that molds do not occur, even in small amounts, I think it would be safe.

Mr. Goodrich: I think that that is all.

The Witness: There is one other point that I am reminded of by that question, and that is this; on which

1698 I can furnish no evidence, but I would like to bring it out as something to be thought about: That is this distinctive white flour going to be so much more nutritious

that we will have more weevil trouble with this kind of flour than with the ordinary white flour.

Mr. Goodrich: No evidence is available on that?

The Witness: Not to my knowledge.

Mr. Goodrich: That is all.

Presiding Officer Willcox: Have you any questions, Mr. Campbell?

Mr. Campbell: I have no questions.

Cross-Examination by Dr. Scott.

Q. Dr. Williams, were you present at the hearing, this flour hearing, on September 11, 1940, and are you familiar with the testimony on pages 396 to 430 of the transcript of record?

I say, were you present at the flour hearing on September 11, 1940, and have you read pages 396 to 430 relating to vitamin D in the transcript of record?

A. I was not present on that date and I can't identify those pages. I have read some of the testimony taken at that time.

Q. That was testimony that was taken specifically relating to Vitamin D. You stated that you were opposed to the addition of Vitamin D to flour because you did not want to get too many of these vitamins in for fear that the cost would be increased, is that your main objection?

1699

A. Yes, that is my main objection.

Q. Are you aware of the fact that flour enriched with Vitamin D has been on the market for five years?

A. No.

Q. Are you aware of the fact as to the cost of that flour? Do you know if it has been increased in cost any?

A. No, I don't know.

Q. Are you aware of the fact that bread baked from that flour has been sold to consumers at no increase in cost?

A. I have been aware of bread with Vitamin D in it had been sold.

Q. Have you been aware that there has been no increase in cost due to the Vitamin D?

A. So I have understood, yes.

Dr. Scott: That is all.

Cross-Examination by Dr. Strowd.

Q. Dr. Williams, you said that in the testing of the assay of biscuits or bread made from self-rising flour, if I understood you correctly, that there is a loss of 40
1700 per cent, is that correct?

A. Yes, I think that that is a fairly typical figure. My own studies of the matter have not been of sufficient extent to justify my saying that that is the minimum to which it can be kept down.

Q. Did you happen to know the formula of the self-rising flour?

A. No, I don't recall it now.

Q. You would not know, then, what the pH of it nole or crumb was after the biscuits were baked?

A. No, I can not give that. I can not recall. Obviously it is true in the case of the self-rising flour that a measure of protection can be afforded against this loss of thiamin by suitable adjustments of the basic elements of the leavening agent.

Q. By the addition of mono-calcium phosphate in addition to that normally required for soda?

A. Yes.

Q. Now, in the baking of baking powder biscuits, where you take plain flour and use baking powder, if the baking powder had a relatively high pH, you naturally would expect a loss, wouldn't you?

A. Yes.

Q. Baking powder sometimes runs as high as 7.5 pH?

A. Yes.

1701 Q. But if you used the phosphate flour, say half a per cent more calcium phosphate or its neutralizing equivalent, and bake that, that would naturally tend to bring down the thiamin loss, wouldn't it? Wouldn't you judge so?

A. Yes, I should.

Dr. Strowd: Thank you.

The Witness: It is precisely because I think that that sort of condition must be taken into account that I brought that matter up.

Dr. Strowd: Thank you.

Presiding Officer Willcox: Any other questions? Are there any further questions of Dr. Williams? (No response.)

If not, the witness is excused.

(Witness excused.)

Presiding Officer Willcox: I think that we might take a recess for a few minutes.

(Recess.)

1702 Presiding Officer Willcox: We will proceed.

Mr. Campbell: I would like to make a motion that the testimony of Mr. C. M. Hardenbergh for the Commander Larrabee Milling Company, in connection with Section 15.000, appearing on pages 396 to 398 inclusive of the transcript of the record, be incorporated by reference in this present proceeding with reference to a proposed standard of identity for this specialized flour, or vitimized flour.

(Whereupon, the then following discussion, by direction of the Presiding Officer, was not placed on the record.)

Mr. Campbell: This testimony refers to a product of the Commander Larrabee Milling Company, containing Vitamin D.

Presiding Officer Willcox: If there is no objection, it will be so ruled.

Whereupon DR. HENRY T. SCOTT assumed the stand as a witness for and on behalf of the Wisconsin Alumni Research Foundation, and having been previously duly sworn, was examined and testified as follows:

Direct Examination.

Presiding Officer Willcox: Dr. Scott, you have testified before in this proceeding and have been sworn, have
1703 you?

The Witness: I have.

Presiding Officer Willcox: And you desire to make a statement in the record, in this proceeding, with respect to Vitamin D?

The Witness: I do.

Presiding Officer Willcox: As an addition to flour?

The Witness: As an optional ingredient, that is right.

At the initial hearings called by the Administrator, Federal Security Agency, on September 7, 1940, I as a witness qualified and offered evidence with respect to vitamin D as an optional ingredient under Section 15.000 outlined in the

Federal Register for August 3, 1940, page 2746. This testimony will be found on pages 398 to 430, inclusive, of the transcript of record of said hearing. My testimony concerning the inclusion of vitamin D in a definition and standard of identity for the flours referred to in said Section 15.000 is equally applicable to the following products referred to in the following sections of said proposed definitions and standards of identity appearing in the Federal Register, issue of Saturday, August 3, 1940, commencing at page 2746:

Section 15.030—Whole Wheat Flour, Graham 1704 Flour, Entire Wheat Flour, identity.

Section 15.040—Crushed Wheat identity.

Section 15.060—Self Rising Flours, Self Rising White Flour, Self Rising Wheat Flour, identity, label statement of optional ingredients.

Section 15.070—Phosphated flour, Phosphated White Flour, Phosphated Wheat Flour, identity, label statement of optional ingredients.

Section 15.080—Farina, identity.

Affidavits requesting the inclusion of testimony at pages 398 to 430 be included by reference was filed with the Hearing Clerk, as all pertinent evidence testified to under Section 15.000 is equally applicable to all the sections above referred to and equally applicable to any other flour or flours that may be defined.

Additional testimony bearing on the subject of vitamin D as an optional ingredient appears at pages 753, 754, 755, 756, 762, and 763. The latter testimony was presented by a government witness (Dr. Nelson) who testified that "of prime importance is the question of whether flour is a suitable carrier so that the vitamin will not deteriorate either in the flour itself or after it has been subjected to any cooking or baking process, and also whether food fortified with vitamin and mineral actually reaches the group of people who should be benefited."

1705 Additional testimony relating to this point continues on page 755 of the transcript of record. On page 756, minimum quantities per 6½ ounces of flour are suggested.

On September 16, 1940, Section 15.080, Farina identity was considered. Testimony by Dr. Gunderson appears at pages 1021 to 1024, inclusive, of the transcript of record relating to vitamin D as an optional ingredient. This testimony and the testimony I have already given, pages 398

to 430, is equally applicable to any new flour defined. With further respect to vitamin D as an optional ingredient in flour and cereals, we are not here asking for something new nor undefined, but are here justifying a product that is already very well known as a commodity in common use for the past several years for reinforcement of foods, for which methods of assay and analysis have been established by the U. S. P.

In the testimony already referred to, evidence has been presented as to the scarcity of vitamin D in nature, its importance in the diet in order to permit optimal use of the minerals calcium and phosphorus; its needs for proper nutrition in infants, adolescents, and adults; also how protracted mineral starvation and lack of vitamin D predisposes to senile osteoporosis, to subclinical osteomalacia.

1795 Evidence has also been presented as to the forms of vitamin D that can be used, range of potencies, and evidence further adducing to the fact that this vitamin D is sorely needed in large cities where sunshine is not abundant, and particularly in the great masses who are in the low income groups that cannot afford to purchase antirachitic agents in order to provide this accessory food factor. This, together with the fact that vitamin D is the scarcest of the known vitamins, renders it imperative to have this factor in commonly consumed foodstuffs, such as flour, bread, and cereals, if the human needs are to be supplied to the poorer classes. Therefore, it is definitely in the interest of the consumer to promote honesty and fair dealing, to permit vitamin D to be included as an optional ingredient in the flour definition under consideration here today, as well as the other flours for which testimony has already been offered.

In the transcript of record to date, no evidence of adverse nature has been offered with respect to inclusion of vitamin D as an optional ingredient. Indeed, it has been recognized that vitamin D is needed by the adult; in fact, in the hearing just closed under 403.J on foods for special dietary purposes, the minimum standard for vitamin D proposed was 400 U. S. P. units daily irrspective of age.

1797 On page 450 of the present hearing, testimony of Dr. Wilder, it was admitted that infants and growing children as well as adults need vitamin D, the latter for prevention of senile osteoporosis. Dr. Wilder testified that the vitamin D needed, assuming plenty of calcium was supplied, could be obtained from sunshine. While it is ad-

mitted that lack of calcium is a factor, it cannot be denied that for proper utilization of calcium, vitamin D is necessary. Foods lacking this factor, leaves sunlight as the only dependable factor. It is my purpose to now prove that sunlight cannot be depended upon to supply this factor, and the data which follows all bears on this point.

The first quotation which I should like to make is from the Journal of the American Medical Association, Volume 99, page 125, For July 9, 1932. The article is entitled "Ultra-Violet Irradiation Useful for Therapeutic Purposes," by W. W. Coblentz. Dr. Coblentz is of Washington, D. C., and is associated with the Bureau of Standards. I have just one short quotation from this paper, although it is all of importance, and the quotation which I would like now to read is as follows:

"The ultra-violet unit of doseage cannot be a concise tangible specification like a quinine pill."

Mr. Presiding Officer, I offer five of these reprints
1708 in evidence.

Mr. Goodrich: That will be the Wisconsin Alumni Research Foundation's Exhibit "S".

Presiding Officer Willcox: Is there any objection to the receipt of this reprint in evidence? If not, it will be received.

(The document above referred to was marked WISCONSIN ALUMNI RESEARCH FOUNDATION EXHIBIT "S", and received in evidence.)

The Witness: The second quotation is from the Journal of the American Medical Association, Volume 109, page 809, for September 4, 1937. This appears under "Queries and Minor Notes," in the Prevention of Rickets by Sun Exposure. I shall make only one short quotation, which is imperative, and I now quote:

"From experience with a group of infant welfare babies for who only direct exposure to the sun was relied on as prophylaxis against rickets during the summer months, it was found that nearly 50 per cent of the babies showed clinical signs of rickets in September. In cities in the temperate zone, such as New York, it would seem advisable if possible, to supplement the sunlight with small amounts of additional antirachitic agents in order positively to prevent the development of rickets."

1709 Mr. Presiding Officer, I submit five copies of this in evidence.

Mr. Goodrich: I move that the parts quoted be marked.

so that there will be a notation in the reprint of the part offered.

The Witness: They are already underlined in this.

(Whereupon, the then following discussion, by the direction of the Presiding Officer, was not placed on the record.)

Presiding Officer Willcox: The second reprint will be received and marked Exhibit T.

(The document above referred to was marked WISCONSIN ALUMNI RESEARCH FOUNDATION EXHIBIT "T" and received in evidence.)

The Witness: As to the effectiveness of sunshine as an antirachitic factor, I would like to review very briefly for a moment the spectrum.

First of all there is the electro-magnetic spectrum, which starts from zero and goes up into the radio waves. The ultra-violet region is roughly from 50 to 400 angstrom units.

Now, when it comes to the ultra-violet, the ultra-violet is generally regarded as the region in the spectrum which prevents rickets in a child or creates vitamin D in a plant or animal. Now, curiously enough, the short range 1710 ultra-violet is not effective, and it is only a very small range from 297 to 313 angstrom units that it becomes effective.

Now, when it comes to the sun spectrum, in comparison to artificial sources such as quartz mercury or carbon arc, the sun spectrum is active only in a very, very small refined region, and that has been measured at sea level on a very clear day, and the amount of ultra-violet that reaches sea level is less than one per cent. Now, if there is any fog, if there are clouds, or dust or smoke or anything in the air, that ultra-violet is filtered out, just like your common window glass filters out all of your ultra-violet because of the fact that it contains iron and lead as a contaminant.

I should like to offer five copies of this chart in evidence, Mr. Presiding Officer, in order to make it simpler when the transcript of the record is considered.

Presiding Officer Willcox: Is there any objection? If there is no objection, this will be received and marked as Exhibit "U".

(The document above referred to was marked WISCONSIN ALUMNI RESEARCH FOUNDATION EXHIBIT "U" and received in evidence.)

The Witness: Now, if you have a lamp and you can control all of your conditions, you do not run into all of that difficulty because you are either irradiating the
1711 food or irradiating the individual in a room in which the forces of nature are not at work.

The next chart which I would like to refer to relates to the clear days and hours of sunshine for large United States metropolitan areas. As you know, we started out with Atlanta, Georgia, and we run through cities like Chicago, Denver, Louisville, Minneapolis, Oklahoma City, and San Francisco and San Diego, and Washington, D. C.

Now, if you will take any series of days for any given month, January or July, let us take January and July. You note the number of clear days that are there in any one particular section.

Let us take the city that we are in now, Washington, D. C. In January, according to the United States Weather Bureau, you had nine clear days, that is the average number of clear days during January. During February, it is the same; during March you have an average of ten clear days. In April you have 11. In May you have 11. In June you have 11. In July you have 11. And in August there is 11; and in September 12, and October 14, getting up into the fall; and November it drops back to ten, and in December it is ten.

In other words, say out of the average thirty days of the month you only have nine, at the most ten clear days and yet you want people to depend upon the sunshine
1712 for vitamin D, remembering that the sun is only effective when it is up overhead and is coming directly upon us.

Mr. Presiding Officer, I offer five copies of this chart in evidence.

Presiding Officer Willcox: If there is no objection, it will be received and marked Exhibit "V".

(The document above referred to was marked WISCONSIN ALUMNI RESEARCH FOUNDATION EXHIBIT "V" and received in evidence.)

The Witness: The next chart is taken from studies which were made in the City of Detroit. Now, when you want to determine whether the sunlight is effective, or is doing its job or not, you have what is called a Minimal Erythome Zone, a minimal Erytheme dose, in which the individual out in the sunshine say for an hour or so, exposed with most of the body exposed to the sunshine, develops a

characteristic redness. You gentlemen who play golf probably have noticed that if you go out on the golf course in the middle of the day, sometime during the day you get red. Now, you get an overdose, because of the fact that you take too much at one time, and probably do not go out again, and you get a little more later on, until you develop a tan; or a protective pigment during those hot clear days. At that time you are not getting a good regulation of the amount of "D" from the sunshine.

1713 However, this table, this chart shows that only during the months of July and part of August, beginning with a little in May and a little in June, are you able to get or obtain this minimal Erytheme dose. Any of the other months during the year which I have not quoted; if you were outside in Detroit you would not get any appreciable amount of Vitamin D from the sunshine because of the fact that your clouds or your fog or your smoke—probably your smoke from your large industrial centers was cutting off the ultra-violet which was supposed to form vitamin D.

Mr. Presiding Officer, I would like to offer five copies of this chart in evidence and also five copies of the reprint in evidence from which this chart was obtained.

Presiding Officer Willcox: Does that reprint explain more fully than this chart?

The Witness: I just wanted to save time, sir.

Presiding Officer Willcox: If there is no objection, these will be received and marked respectively Exhibits "W" and "X".

(The documents above referred to were marked WISCONSIN ALUMNI RESEARCH FOUNDATION EXHIBITS "W" AND "X" and received in evidence.)

The Witness: The next chart is really a follow-up on the one which I have just discussed, although it ap-

1714 pears in another reference, and appears in the Archives of Pediatrics for July of 1939. This article as well as the previous one is by Doctors May and Wygant of Detroit, in which they engaged in a series of investigations on a large number of children in that city, attempting to correlate the amount of rickets in the city with the value of the sunshine and other sources of vitamin D for the prevention of rickets.

Now, this chart shows the distribution of cases of rickets in the City of Detroit. Again you will notice that where the large number of spots appear is your slum centers, and

where the poor people cannot afford to buy vitamin D in the form of antirachitic agents. They cannot afford to buy them and they must be supplied. That is why the supplying of Vitamin D in some commonly consumed food on a communal scale will result in much better nutrition.

This chart is just offered in evidence, five copies are offered in evidence to show that in correlation with the reprint of the article, just how this question affects the poorer classes and while there is much pertinent data in the reference which I am citing here, I would be content to just offer in evidence this document and save time.

Mr. Goodrich: This map is included in the re-
1715 print which you already have offered?

The Witness: Yes.

Mr. Goodrich: For that reason I move that it not be incorporated in view of the number of exhibits already in, and the probable length of the record. I see that it would serve no real purpose.

Presiding Officer Willcox: Did you wish to duplicate this?

The Witness: Either that or these copies, Mr. Presiding Officer. This reprint has already been admitted in evidence.

I will just introduce the charts, then.

Presiding Officer Willcox: If there is no objection, this chart will be received and marked Exhibit "Y".

(The document above referred to was marked WISCONSIN ALUMNI RESEARCH FOUNDATION EXHIBIT "Y" and received in evidence.)

The Witness: The next chart which I would like to refer to is taken from a paper entitled "Failure of Abundant Sunshine to Protect Against Rickets," by C. Ulysses Moore and associates. This reprint was published in the American Journal of Diseases of Children, Volume 54, of December, 1937.

In this study, which was conducted in Portland,
Oregon, and also in San Diego, California, a thousand
1716 children were engaged in the study, or were participants in the study; and several criteria were employed to determine whether the children had signs of rickets, remembering that these were all pre-school children, and the various signs were the head, the chest and the extremities. That is the head was examined for flatness and bossing, the chest was examined for pigeon or funnel shaped, the rosary, the groove, enlarged epiphyses

or joints, and the varum, which refers to knock knees and then flat feet.

Of all of the children examined, the number which showed signs of rickets was 95 per cent in Portland, Oregon, and 73 per cent in San Diego, California. It was slightly less in San Diego, but not a great deal of difference, if one considers that in the Southern area that section of the country there should be abundant sunshine, and if effective this should be down to a lot less than 73 per cent.

This chart and the reference to this work is completely covered in the reprint from which I have taken the chart and I would like to offer five copies of these reprints in evidence.

Presiding Officer Willcox: If there is no objection, these will be marked as Exhibit "Z."

(The document above referred to was marked WISCONSIN ALUMNI RESEARCH FOUNDATION EXHIBIT "Z" and received in evidence.)

1717 The Witness: Another chart which I would like to refer to is the one which appears in the Public Health Bulletin No. 224, from the U. S. Treasury Department. In this series of investigations which was conducted in Pittsburgh, Pennsylvania, Salt Lake City, Cleveland, and Baltimore, a study was made at various times of the year, and even though the whole year, of the average number of tons of dust deposited per square mile per year.

In the City of Pittsburgh, it amounts to 1,031 tons per square mile. In your neighboring city of Baltimore, it represents 1876 tons of dust per square mile. Three miles from Baltimore you have 800 tons per square mile, and ten miles you have 340 tons.

Therefore, in the City of Washington, you are getting some filtering out of the Ultra-Violet ray of the sunshine due to the soot and smoke and dust which comes from the City of Baltimore.

In Salt Lake City, and this data was collected by the Bureau of Mines, you have 349 tons per square mile, and all of that comes from the industrial centers.

In Grafton, West Virginia, you have 1876 tons of dust per square mile, and yet you expect the sunshine to come through all of that dust, to create vitamin D in the human skin, when the ultra-violet effectiveness as measured and referred to in the studies which I have previously
1718 introduced from the City of Detroit—you can see that

you have got a lot of factors at work which are cutting out the ultra-violet from the sunshine.

Add to this the fact that nature probably originally intended us to get that from the sun, but we are dressed in clothes, modern civilization has inhibited our opportunity to get the vitamin D from the sunlight, and it is because of the fact that we are only out in the late afternoon and the early morning when the ultra-violet is practically nil, because if the sun comes to the earth obliquely there is no ultra-violet given off.

I would like to offer five copies of this chart in evidence, Mr. Presiding Officer, and I do not have reprints of this article.

Presiding Officer Willcox: If there is no objection, this will be received and marked Exhibit "AA".

(The document above referred to was marked WISCONSIN ALUMNI RESEARCH FOUNDATION EXHIBIT "AA" and received in evidence.)

The Witness: The last chart which I have here refers to the condensation nuclei in the atmosphere. Due to the fact that you have given off gases from industrial centers, and from combustion of various plants, you have sun spots which are caused by these condensation nuclei.

This is taken from Public Health Bulletin No. 233 of the United States Treasury Department, a Public
1719 Health bulletin, and it takes in various cities including Washington, New York, New Orleans, and San Francisco, and so on.

Now, the short ultra-violet which is coming through is stopped by the condensation nuclei, which are caused or come from the fact that sulphur dioxide, SO_2, is given off in the air, and that is catalyzed to sulphur trioxide, and the result is that that becomes hydroscopic, and with this condition the tendency of condensation nuclei to further filter out the ultra-violet is very much apparent.

I should like to offer five copies of this chart in evidence, Mr. Presiding Officer.

Presiding Officer Willcox: If there is no objection, this will be received and marked Exhibit "BB".

(The document above referred to was marked WISCONSIN ALUMNI RESEARCH FOUNDATION EXHIBIT "BB" and received in evidence.)

The Witness: There has been considerable written in various text books, and various papers as to the effective-

ness of the sunshine, and I perhaps could go on and quote any number of authorities. However, I picked out a few, this one is from Dr. Ethel M. Luce-Clawson, the article appears in vitamins, a publication of the American
1720 Medical Association, for 1939. On page 562, she tells you how to carry out the technique of helio-therapy, which means sun treatment, or light treatment, and it is as follows, and I quote:

"At first the legs are exposed, the feet being protected by socks in the early spring and summer. The first exposure should be for ten minutes, and is to be regarded as a preliminary test to gauge the susceptibility of the individual. On each successive morning the treatment may be prolonged five minutes, until the infant has been exposed for one-half hour daily.

"On alternate days the arms are treated in the same way, at the beginning for ten minutes, and increasing the period as with the legs. As soon as the weather permits the trunk is exposed, the baby being clad merely in a diaper with the hands and feet covered. The head should always be protected with a light cap. The eyes may be shielded. Mothers and nurses are often greatly concerned lest the sunlight prove harmful to the eyes."

And I could go on and quote. Now, the question is that you want to supply vitamin D to the poor people. Take the family with four or five kids, and the mother has all of the house work to do. She can't have the opportunity to carry on this technique and irradiate the
1721 youngster out in the sunshine. They refer to a nurse here, and poor families don't have nurses, and they don't have maids.

The next quotation is from Dr. Alfred F. Hess, in his book on Rickets, Tetany and Osteotomoclasis. On page 108 he has this to say:

"Very little of the antirachitic irradiation is able to penetrate clothing material. This question was put to test in an experiment in 1923 by employing as filters cotton and woolen goods of various meshes and using the carbon arc lamp as the source of ultra-violet rays. It was found that if the cotton fabric was interposed between the animal and the lamp, 3 units of irradiation were required to bring about protection; whereas if the material was somewhat heavier and more closely knit, only slight protection could be brought about even with this intensity."

The next quotation that I should like to make is from

the text, "Newer Knowledge of Nutrition," by McCollum, Miles and Day. On pages 378 and 379 he has the following to say about the administration of Vitamin D during the summer season.

"The question of whether the administration of Cod Liver Oil or other source of vitamin D should be continued through the summer months is often raised. 1722 Parke points out that although theoretically this is not necessary, practically it is better to continue feeding vitamin D throughout the year. The sunlight in the cities often contains little or no ultra-violet rays and is therefore not effective in preventing rickets."

There is another quotation on page 379 with reference to the question of air pollution, and I quote:

"The loss of solar ultra-violet due to a sooty atmosphere is of importance from a public health standpoint."

The last quotation which I have is from Lorenz, "Physiological Effects of Radiant Energy."

Mr. Goodrich: Is this along the same lines, about administering vitamin D? I think if so it is my opinion that the record is ample on that now, and in order that we may proceed along with this, I will object on behalf of the Food and Drug Administration to reading in any more quotations along the same lines, the ground being that it is cumulative, and in addition to what is already in.

The Witness: This is entirely pertinent and relevant.

Presiding Officer Willcox: If you have only one more excerpt, you want to put in the record, I won't 1723 sustain the objection at this time.

The Witness: It is all along the same line, and I agree with you, if you are satisfied, I am.

Mr. Goodrich: I think that if we can be satisfied that this is the same evidence, that it won't help anything to add another quotation, and now I believe that the record is ample now to demonstrate all of the points on this, and the conclusions can be drawn on the basis of the full information.

My idea was that the testimony was cumulative, and in the interest of speeding up the proceedings that we eliminate what we can.

The Witness: Well, the point is that there has been testimony in the transcript of the record that you could get enough vitamin D from the sunshine, and I am perfectly willing—but I am merely trying to point out that you cannot, and it cannot be depended upon, and the refer-

ence which I was about to quote from was to merely confirm all of the previous quotations that I had already read.

I might say that if necessary I could bring down a whole library here, and could get you hundreds and hundreds of quotations.

Mr. Goodrich: That is what I am afraid of.

The Witness: But the point is, it is not in the
1724 interest of the consumer to promote honesty and fair dealing to say that you can get enough vitamin D from the sunshine, when we can show you reference after reference which will adequately dispute that, and why anyone will say so, is beyond my scope of imagination.

Then, with your admission of enough of this in evidence, I will proceed with my conclusion.

The above citations in evidence prove quite conclusively that the sunlight cannot be depended upon to supply vitamin D; therefore, vitamin D must be supplied to the populace on a communal scale through the medium of a commonly consumed food, such as milk, flour, bread, and cereals, that is cheap, universally available, and known to be consumed by the masses. Therefore, to deny vitamin D as an optional ingredient in a flour would not be in the interest of promoting honesty and fair dealing among the consumers.

In closing, I would like to request that this testimony, as well as that previously given, pages 398-403, inclusive, in the transcript of record, be considered by the Administrator when a definition and standard is written so that vitamin D may be included as an optional ingredient.

Presiding Officer Willcox: Have you any questions, Mr. Campbell?

1725 Mr. Campbell: No.

Cross-Examination by Dr. Strowd.

Q. Doctor, I wonder if in those charts that you have showing the prevalence of rickets there in Detroit, I believe it was, if there was any study made as to the calcium and phosphorus content of the diets?

A. All of the children that I referred to in that study, it so happens, were used as controls, or either later were put on what is called "ricket studies," where the vitamin D was supplied, and Doctors May and Wygant always made it a point to see that plenty of milk was supplied.

In other words, they were pediatricians that were conscious of the proper diet a child should receive, and they were all on evaporated milk, and the result of that is I would say that the calcium requirement was adequately supplied unless the child was premature, or was malnourished, or allergic to milk.

Q. What age would they go up to?

A. They went up from birth to two years, that is the children were taken at birth, and then they were followed up to two years of age.

Mr. Goodrich: I have no questions.

1726 Presiding Officer Willcox: If there are no other questions, I think that that will be all.

(Whereupon the witness was excused.)

Presiding Officer Willcox: I think that this might be an appropriate point at which to introduce the affidavit of Mr. Steenbock, to which I referred yesterday, I think that everyone has had an opportunity to look at that, if they wanted to.

Is there any objection?

Mr. Goodrich: I have no objection.

Presiding Officer Willcox: The affidavit of Dr. Steenbock will be received and marked as Exhibit "CC" on behalf of the Quaker Oats Company.

(The document above referred to was marked QUAKER OATS COMPANY EXHIBIT "CC" and received in evidence.)

Whereupon DR. W. H. STROWD assumed the stand as a witness for and in behalf of the Soft Wheat Millers Association, and having been previously duly sworn, testified as follows:

Direct Examination.

The Witness: I would like to say first of all that I have been very much impressed with the fairness and sincerity of everybody concerned in trying to arrive at a program of maximum benefit to the consumers in this proposed

1727 program of flour fortification, or vitaminification, or whatever you want to call it. I believe that Dr. Nelson has in his previous testimony approached this matter in a very scientific way, and I think that the distinguished gentlemen that have testified today have a-

tempted to find a common meeting ground and adjust their points of view with the other points of view that have been presented.

I would be somewhat embarrassed to follow such a distinguished array of scientific talent were it not for the fact that I happen to have read some of the previous statements of some of them, and find how widely contradicted they are by the statements made today; so I had better start by making a reservation that all parts of my previous statements not in accordance with my statements here now, are hereby repealed.

At least I can say what I have to say in all fairness and without criticism of any of those with whom I may seem to be in disagreement, that at least there seems to be no pride of opinion.

I am in agreement with the testimony of Dr. Wilder and Dr. Sebrell and others who agreed with them, as to the requirements of vitamin B_1. I want to say in this connection that B_1 is according to all data, the most widespread deficiency in diets of all classes. I can understand Dr. Wilder's opinion, and the reasonableness of his opin-
1728 ion, and the opinion of the Millers committee, that B_1 should be the one required mineral or vitamin ingredient.

As to the quantity of B_1 proposed by Dr. Wilder and others, there might be some argument presented against it, but where there is doubt as to the adequacy, I feel that we should, if we are going to err at all, err on the side of liberality, and trying to assure the customer, or the consumer, of an abundance of the thiamin hydrochloride.

I think when it comes to a question of the optional ingredients we should take a similar attitude of liberality. I have been rather surprised frankly at the attitude with reference to calcium, and also with reference to phosphorus. Calcium has been adopted by the British Government, phosphorus has not, but I heard no evidence presented in support of the view that phosphorus was not needed in the diet, and I know of no justification of where iron should be proposed as, for instance, an essential ingredient and calcium should not.

As stated I am inclined to believe that B_1 should be the one ingredient as the one universally needed, and I believe, though, that in a great majority of the diets of America, the data actually show that calcium is the element of outstanding deficiency.

I wish to refer you to Bulletin 507, which has been
1729 discussed by several previous witnesses, and call your attention to page 50 and 51 of this circular, and tables 30, 31 and 32.

Tables 30 and 31 show a suggested calcium allowance of 1 gram of calcium per day, for children under 20 years; of .88, of women 20 years and over, and .68 men twenty years and over.

In the Federal Register, the Food and Drug Administration has recommended as a minimum allowance, .75 grams.

In a generally used diet like flour, I think that we should take the top allowance, or in other words a figure of one gram, and that is not in contradiction of the Food and Drug Administration's proposed limit of .75, but also carries with it certain overage to assure ample quantities.

Now, with reference to phosphorus, the range is from 1 to 1.32, that is the range for children and adults. In adults they give the higher figure, more phosphorus than for children, and in the case of calcium they give the figure higher for children than for adults. But as I say, in a generally used flour, you should take the top figure as a reasonable one.

Now, Table 32 shows the phosphorus and calcium content of American diets. There are approximately 30 per cent of the diets shown, and nearly all of them for the 1730 low income groups, that are deficient in phosphorus.

In the case of calcium, 80 per cent of them, approximately, are deficient.

I don't believe, without checking it over very carefully, that there is any more outstanding deficiency with reference to any other dietary accessory, certainly in the case with calcium, and there is less evidence of a deficiency of phosphorus in the case of some accessories that have been mentioned.

Now, that may be considered as a theoretical proposition, and those allowances too liberal. Under date of August 1928, there was published by the Soft Wheet Millers Association a bulletin entitled "The Nutritive Value of Various Types of Bread and Biscuits," in certain typical diets, with special reference to their effect on bone.

In these studies we took some seven or eight diets which are characteristic of the South. For instance, here is one diet, meat, butter, Irish potatos, cabbage, corn

meal, and bread or biscuits. And the other diets were amplified with reference to that.

Now, we studied these diets, in the growth of experimental animals, and made the only variable the type of bread used, we used self-rising flour, and compared it with biscuits made with non-phosphate baking powders, or alum phosphate baking powders, and with yeast
1731 bread, and the yeast bread made with milk and made with water, and commercial breads, and then we carried as a control ration the stock ration which was at that time considered to contain all of the ingredients of the diet, a fully and completely balanced diet. It had the following composition: Corn, yellow corn, 60 parts; whole milk 20 parts, caisin 10 parts, oil meal 6 parts, alfalfa meal 2 parts, calcium carbonate 1 part, and salt 1 part.

In that diet we determined, or in the comparison of that diet with the different types of bread, we measured the gain in weight, and also the average ash content of the humerus and femur, those are the typical bones.

We found that while the self-rising biscuits did not have quite the same good effect as the control diet, it was far superior to all of the others. There were some seven or eight diets with which we made comparisons, and we found generally speaking, the same results, showing unquestionably that the calcium-phosphate as an ingredient of self rising flour, was a very important factor in nutrition in those diets.

I haven't the usual number of copies, but I would like permission to file five copies with you within ten days, if that would be all right.

Mr. Goodrich: File one copy, and supplement the others.

1732 The Witness: I will do that.

Presiding Officer Willcox: Is there any objection to the receipt in evidence of this exhibit, entitled "The Nutritive Value of Various Types of Bread and Biscuits"?

If not, it will be received, and marked as Exhibit "DD" on behalf of the Soft Wheat Millers Association.

(The document above referred to was marked SOFT WHEAT MILLERS ASSOCIATION EXHIBIT "DD" and received in evidence.)

1733 The Witness: Now, as a further, or projection of this study, I have recently examined some records of

the State Board of Health, of North Carolina, which is unique among the States with reference to the different types of flour consumption.

As you all probably know, North Carolina is bounded on the East by the Atlantic Ocean and on the Western part it is in the middle of the mountains. For some reason which I won't try to explain, in the eastern part of the State, family flour consumption is almost 100 per cent self-rising, and in the western part of the State it is 30 to 35 per cent.

I have a wire from one of the mills which sells throughout the State in corroboration of that statement, which I don't happen to have with me this afternoon. I forgot and left it at the hotel, but I would be glad to enter that as an exhibit, if I may. I think that that is a widely recognized fact.

Now, in the eastern part of the State the statistics compiled by the U. S. Bureau of Census show that the per capita production of milk is about 50 quarts per year. I think that that would be affected some by condensed milk or cheese or things like that. I can only talk about the production. I don't have the figures for consumption.

The per capita production of milk is approximately 1734 50 quarts per year, and in the western part the suggested allowance of milk per day is, as you know, about one quart, or 365 quarts per year, so that the production of milk is only one-seventh of the quantity which nutritionists tell us is the optimum quantity of milk to be used on the average.

In the western part of the State, the production of milk is approximately four times as much, or 200 quarts per year.

Now, as I say, those figures are with reference to production. That is the best we can get it. I don't know how you can get it by consumption; it is undoubtedly altered to some extent, probably not a great deal, by the consumption of cheese and condensed milk or something like that. In the west there is probably a good deal that is produced that moves out of the counties, but at least I think that we can fairly say that the average consumption of milk in the mountain counties is more than it is in the Eastern counties.

Now, that data is based on figures from the United States Bureau of Census, for the year 1934.

In 1935 there was a survey made of all of the school children in the State of North Carolina, by counties, through the cooperation of the Director of Oral Hygiene for the State Bureau of Health. Dentists gave their
1735 time to examine the children and make reports on them. That is not published, but the Director has promised me a statement. I only saw him Monday of this week, that is the first opportunity that I had.

These data showed a great many things about the children's teeth, and he said the best criterion of calcium or phosphorous deficiency was in the number of permanent teeth that needed extraction. The baby teeth, I believe he said, received their milk from the mother, and who will, as you know, sacrifice her skeleton for the sake of a child, but the permanent teeth showed that there were twice the percentage of the children in the west needed permanent teeth extraction as compared with those in the eastern counties.

That is to say, there were 16 per cent of the children in the mountain country, had permanent teeth that needed extraction, while there was only 7 per cent of the children in the eastern counties who needed permanent teeth extracted.

Now, I hope I have made my facts that I am trying to bring out clear, that the children's teeth were improved in sections where there was apparently less milk production but almost universal self-rising flour production, showing the great benefits of the calcium phosphate in the self-rising flour.

1736 The data in Circular 507 shows that the poorer classes in the South were better off with respect to calcium and phosphorus supply than in any other section of the country. I have already introduced that statement into the testimony last September.

Now, what effect calcium had that caused that benefit, independently of the phosphorus, I do not know. I do know that the diets are to a considerable extent deficient with respect to the proposed optimum phosphorus allowance. On that basis, I believe not only calcium but phosphorus should be allowed as an optional ingredient, and I say it is optional because with an optimum quantity of milk it would not be necessary, but I do say that it is of greatest importance, especially to the low income groups.

Now, those figures with respect to milk production may seem somewhat inconsistent, but remember this: That the

poor farms in the mountain countries, probably did not get enough milk, even though the production was relatively high there, about 60 per cent of the optimum per capita requirements, but the poor children of the eastern part of the State were large users of self-rising flour, and it is a very significant fact in this Stiebling bulletin that the consumption of cereal products was more nearly constant with respect to flour and meat, for the different age
1737 groups, than it was in any other type of foodstuff, and they probably used actually more flour than the well-to-do classes because it is the cheapest source of energy.

That is all.

Mr. Campbell: Your testimony is offered on behalf of the Soft Wheat Millers Association, is it?

The Witness: Yes, sir.

Cross Examination by Mr. Goodrich.

Q. I don't remember whether you suggested all of the forms for the addition of calcium and phosphorus in connection with your testimony last time. I believe that you mentioned dicalcium carbonate and calcium phosphate. Are there other calcium salts suitable for addition to supply the calcium requirements for the dietary?

A. I don't know, sir. I can't say that. I can say that I approve of the three types of phosphate, and also calcium carbonate, and I don't know about calcium pyrophosphate. It is not made a commercial article as yet. I see no objection to it, from the general information about pyrophosphates, it would probably be satisfactory, but I don't believe that that is available at the present time commercially. Those are all that I know about.

Q. And the phosphorus compounds from the same substances?

1738 A. Yes, sir, I think that generally speaking. I mean the information is that all forms of calcium, even calcium silicates which are very sizable, can be used as a source of calcium. However, I would not recommend that, but I mean the use in mineral forms is very broad, as a type of inorganic phosphate, or inorganic calcium compounds.

Q. This bulletin to which you have referred is the bulletin of the U. S. Department of Agriculture, I believe?

A. Circular 507, U. S. Department of Agriculture, the Stiebling bulletin that has been referred to a number of times.

Q. When you were giving the figures and you gave the calcium requirements, you said point 132, and I believe that it should be 1.32, should it not?

A. Yes, it is 1.32.

I would like to call attention to the fact, incidentally, that I asked Dr. Stiebling if she thought those figures were reasonable, and she said that she thought they were.

Mr. Campbell: I wanted to have the record show what those units were? That is, are they grams, or what?

The Witness: That is suggested allowance in grams per day.

1739 Mr. Hardenbergh: What is that, how much in flour? Are you recommending anything in flour?

Mr. Goodrich: He made his recommendation before; 6½ ounces.

The Witness: The recommendation adopted by or made by Dr. Nelson, and supported by Dr. Wilder, and by Dr. Sebrell, and Dr. Jolliffe, I believe, is satisfactory to me.

Mr. Hardenbergh: That is what I wanted to get.

Mr. Goodrich: I believe that you first suggested that 6½ ounces on the basis of the national per capita consumpetion of flour, did you not?

The Witness: I don't remember. I divided the production of flour by the population, yes, sir.

Mr. Goodrich: I think that that is all that I have.

Just a minute, please:

By Mr. Goodrich:

Q. Your association is primarily an association of self-rising and phosphate flour producers, is it not?

A. It is an association of millers of soft wheat flours. Most of our trade is to the family, rather than to the commercial baker, so that we only sell some commercial cake flours, and some commercial cracker flours, but by and large it is a family flour, and that flour is either

1740 self-rising, or phosphated flour.

Q. Do you recommend that this vitamin flour standard as suggested by the National Millers Federation be extended to include a self-rising flour with these same additions and of self-rising vitamin flour as a separate standard of identity but just having self-rising flour, whether it be self-rising or without leavening ingredients?

A. We certainly want self-rising flour included in the

nutrition now, or vitamin flour, if you want to call it that, and it is a matter of administration as to which way you do it. We certainly want it included.

Mr. Campbell: And also in phosphated flour?

The Witness: Yes.

Mr. Campbell: I did not know that you made that clear.

By Mr. Goodrich:

Q. In your original testimony in September, I believe that you suggested Vitamin B_1, calcium and phosphorus. I have forgotten whether you suggested nicotine acid or riboflavin, either one; I don't believe you did.

A. I suggested at that time B_1, calcium and phosphorus.

Q. And you sustained those—

A. And I am using nicotinic acid in my flour, and I approved of iron and B_2 as optional ingredients.

1741 Q. Do you subscribe to the theory advanced by Dr. Sebrell and Dr. Wilder and others that the additions should be made in combination, that is in combination of B_1, nicotinic acid, iron and then with the optional ingredients of riboflavin, calcium, phosphorus, and others? What is your position on that?

A. Well, as I said, Mr. Goodrich, I think that B_1 would be a basis or should be the required added ingredient but that we should be very liberal in the optional ingredients. We have all had to revise our opinion, since I started, I have got to modify the formula of my Bi-cap flours, to meet this situation but to make it too ironclad, I don't think so.

For instance, you get in the dairy section, where people are accustomed to drinking milk, they may need B_1, and they need nothing else, and I am trying to look at the thing from a broad national picture, and not from the Southern standpoint, and I think on that basis B_1 should be the only added ingredient and I do think that these others may be necessary to meet certain cases, and certain regions, certain income groups, and with respect to the South I think that calcium and possibly phosphorus exceeds in importance B_1 but that does not want to bind me. I would not want to bind the Minneapolis mills to sell it through a dairy section of Wisconsin, you see.

1742 Q. You have had experience with diet deficiency diseases, I take it?

A. Well, I have sort of in a certain way; I don't know. I am not a physician, you understand, but I have studied the dietary, the mass dietary requirements of people in

the South, to a certain extent, not as a physician, but as one interested in trying to make flour serve them in the most efficient way.

Q. It is true, then, that the presence of one diet deficiency is usually accompanied by other dietary deficiencies which need correction?

A. I think that that would be true of the low-income groups. I don't believe that is true with respect to the high income groups. That is not any personal experience of mine but from reading the opinions of authorities on the subject, and observations among my friends and all of that kind of thing. You will find that the B_1 deficiency is the thing that they are suffering from, and the addition of B_1 in tablet form takes care of that situation very well; that is why I say that I believe B_1 should be the single required ingredient.

Q. I believe Dr. Wilder stated that it was quite difficult to produce a single deficiency, without the other complications, and I believe that he referred specifically to B_1, leaving the inference to me, at least, that where
1743 there was a B_1 deficiency, there would be a riboflavin and nicotinic acid deficiency along with it.

A. Dr. Wilder is much better qualified to pass judgment on a matter of that sort than myself. I had gotten the different idea mainly from the statements of Dr. Wilder and others, and now I may be confused on it. You are getting over my head now, because I am not a physician and I can't answer.

Mr. Goodrich: I think that that is all.

Presiding Officer Willcox: Any further questions?

Cross Examination by Dr. Scott.

Q. Would you have any objection to the addition of Vitamin D as an optional ingredient in phosphated flour and self-rising flour?

A. No, sir. On the contrary, I favor it. I am sorry that I overlooked mentioning it.

Cross Examination by Mr. Campbell.

Q. Is it your idea, Dr. Strowd, that if vitamins and minerals are permitted either as requirements or optional ingredients in a separate standard of identity for flour, that you would desire separate standards of identity

1744 for self-rising flour, and phosphated flour, with the permitted ingredients either as requirements or optional ingredients as they would exist in this proposed definition and standard for Vimin flour?

A. Yes, sir.

Mr. Gilbert: Would you explain what that is? We could not get that.

(Discussion off the record.)

Presiding Officer Willcox: Any further questions?

Mr. Campbell: Then I will ask this question:

By Mr. Campbell:

Q. Assuming just for the purpose of argument that this new standard of identity for flour with vitamins and minerals added was to be called "Vimin Flour" it is my understanding that you would also want a standard of identity for Vimin self-rising flour, and Vimin phosphated flour, is that correct?

A. That is correct.

Presiding Officer Willcox: I guess that will be all.

(Witness excused.)

Presiding Officer Willcox: It is 5:15. I am prepared to go on for another forty-five minutes or so; if there are any other witnesses that we can take in that time, or perhaps we had better continue a little longer anyway 1745 even if we don't finish with another witness.

Mr. Hardenbergh: Our next witness is Dr. Sherwood, and he is not here now.

(Discussion off record.)

Mr. Goodrich: I move that we adjourn until tomorrow morning.

Presiding Officer Willcox: We will adjourn until 9:30 tomorrow morning.

(Whereupon, at 5:20 o'clock p. m., the hearing was adjourned until 9:30 o'clock, a. m., Friday, November 15, 1940.)

1748 Appearances:

As heretofore noted, with addition of

Charles W. Ballard, 124 Claremont Ave., Mount Vernon, New York, appearing on behalf of Hecker Products Corporation.

F. A. Neuberg, Rivervale Road, Rivervale, New Jersey, appearing on behalf of Monsanto Chemical Company, Westvaco Chlorine Products Corporation, and Victor Chemical Works.

1749 PROCEEDINGS.

Presiding Officer Willcox: We will come to order, please.

Mr. Thode: I would like to call Dr. Sherwood. Whereupon

DR. REGINALD C. SHERWOOD was recalled as a witness for and on behalf of the Millers National Federation, and having been previously sworn, was examined and testified as follows:

Mr. Thode: Please let the record show that Dr. Sherwood appeared preiously in the hearing and was sworn and gave his qualifications.

By Mr. Thode:

Q. Dr. Sherwood, at the time you testified previously in this hearing, I believe that you stated as one of your qualifications, did you not, that you had in addition to your experience as a chemist some experience in the actual management and operation of a flour mill?

A. That is right.

Q. What was that experience?

A. For five years I was Director and Manager of the Minnesota State Testing Mill, the State experimental flour mill, located in Minneapolis.

Q. Is that a mill which is comparable to commercial mills?

1750 A. That is a commercial mill, fully equipped for commercial operations. Experimentation was conducted there, flour used by the State institutions was produced there, and shipped to these institutions for their ordinary use.

Q. Doctor, have you given any thought to the problems which were mentioned in the testimony of Mr. Hardenbergh, as attendant to the addition of these various suggested ingredients to flour, on any general of wide basis?

A. Yes, I have.

Q. Speaking as a representative of the Millers National Federation at this time, would you have any statement that you would care to make on this general subject?

A. Yes, I would like to make some comments on this subject.

Q. Will you proceed, then, please?

A. First I would like to state that in presenting this testimony I am appearing in behalf of the Millers National Federation, to testify concerning some of the practical problems confronting the industry respecting the maintenance of standards and control of uniformity in the type of vitamin and mineral flours under discussion here. I am endeavoring to discuss the viewpoint of that entire portion of the milling industry as represented in the
1751 Millers National Federation. The following remarks, therefore, have general application to a high proportion of the industry, but the circumstances which they outline, the difficulties which they mention, may not be applicable to each individual mill or to many of the larger mills. In view of the testimony which has been presented here by the Government and by nutritionists, however, the industry while in complete accord and harmony with the nutritional objectives involved, must nevertheless present its view of the effect upon the entire industry and the program as well, if a definition is made so broad as to include a number of required ingredients other than thiamin.

If the program is to serve a general nutritional purpose it must be such that it would be obtainable reasonably by a very high percentage of the mills that manufacture the flour the public consumes. Any involvement which limits broad attainment or delays widespread adoption will tend to defeat the objective for which the program is designed. Accordingly, the Millers National Federation has expressed the view that at this time that it considers it most desirable to aim for a definition requiring only the addition of thiamin, B_1, or thiamin, and the designation of the factors Vitamin B_{12}, riboflavin, nicotinic acid, iron and calcium as optional ingredients.

In expanding upon the general remarks of Mr. Har-
1752 denbergh which he made at the opening of the ad-

journed hearing, I shall outline some of the situations which may make difficult the prompt industry-wide adoption of the proposal in other than the simple form the Federation has suggested.

Several witnesses have given testimony respecting the nutritional advantages of the flours with enhanced Vitamin and mineral value, and the benefit that would result from their public use. My comments will be directed primarily along the lines of existing practical aspects of the additions of these vitamins and minerals.

Upon studying the practical problems involved in manufacturing and controlling uniformity in flours which would conform with the proposed new standards, there are certain facts influencing operations which come to light. It has been mentioned by some of the experts on nutrition that the standard should be written in such a way that production of these flours could be attained by more than one method, and that the basis of the standard should be nutritional and not method of manufacturing. The Millers National Federation approves of the nutritional basis for the standard, and wishes to emphasize further the desirability of considerable latitude in manufacturing operations, by which these nutritional standards will be attained.

1753 The amounts of thiamin naturally present in various fractions of milling, or mill streams, as they are called, vary greatly. In hard wheat milling, which apparently has been rather extensively investigated, somewhat more, perhaps, than soft wheat milling, this variation in thiamin content is as great as 100 to 1, specifically as high as 10 units of thiamin per gram and as low as 1/10th unit per gram. This variation is much greater than that of other wheat components, such as protein, ash, fat, and fiber, for which tests are regularly made.

Variations in riboflavin content in mill streams are large, also, but not as large as the thiamin variations.

While certain relationships exist between thiamin concentrations and ash content, and color of flour, none of these relationships is sufficiently close or dependable to serve as a practical control of thiamin content in flour. Some data have been obtained on the variations in thiamin content of individual wheats. Substantial variations are known to exist, and these seem to be both varietal and environmental in character. Commercial lots of wheat available for purchase by millers show smaller variations than varietal or

experimental samples obtained from small plots of ground.

Nevertheless the variations in commercial lots of
1754 wheat are too large to permit millers to assume a fixed thiamin value for wheat blends. In general, the classes of wheat may be listed in order of descending amounts of thiamin as follows:

Durum; hard red spring; hard red winter, soft red winter.

Limited data on hard white wheats indicate that they fall in the ranges of hard spring and hard winter. There is no sharp division, however, between classes of wheat, but instead there is overlapping, due presumably to environmental influences. These facts are mentioned to show that it may be necessary to assay white blends prepared for milling to determine their thiamin content when long extraction flours are being milled; when mill streams are selected for blending, the thiamin content of the streams, and the finished flours, must be determined.

I have referred to the rather wide variations in thiamin content of different wheats. This may have suggested the possibility of selecting wheats for their thiamin content, thus preparing special wheat mixes for milling these vitamin flours that are superior to the average run in respect to thiamin. Such selection would be impracticable. There is no indication that thiamin content is related to baking value. We must continue to make our selection of wheat for flour milling on the basis of baking characteristics regardless of variations in the vitamin con-
1755 tent.

Whenever new factors become a part of labeling declarations or of guarantees to the purchaser, they become a matter of immediate concern to the manufacturer, for he must determine his ability and his capacity for supporting such label declarations and maintaining uniformity with respect to each new factor. Some general conclusions on this topic appear pertinent on the subject of this hearing, and worthy of inclusion in the record.

Calculation of vitamin and mineral content can not safely be based on the basis of quality of purchased wheat alone, nor upon an extraction of flour of constant relation to the whole grain. Claims for vitamin and mineral content can not be related to constant chemical analysis, physical appearance, or baking characteristics of flours, if natural vitamin content of milling fractions is to be relied upon alone. Definite guarantees of vitamin

and mineral content can not safely be made at present without inclusion of liberal factors of safety to allow for the variables existing in production and in the testing of individual samples. Required factors of safety involve definite costs, and other considerations not evident in the guarantees themselves. Discussions of vitamin and mineral content involving sellers, buyers, and control officials, require added laboratory determinations beyond those
1756 ordinarily employed heretofore for flour and other cereals, with necessary added expense factors, and possibilities of misunderstandings.

I now wish to comment more specifically concerning the manufacture and laboratory testing problems in connection with production with the types of flours under discussion. It will be necessary for mills producing this type of flour to make laboratory tests for vitamin and mineral content to guide their manufacturing departments in production and to insure that the flour offered for sale conforms with the new standards. This will require purchase of equipment and training of personnel, in the case of mills that are now equipped with laboratories. Those mills not so equipped presumably will obtain such service from commercial laboratories; regardless of which way the tests are made, there will be added expense for laboratory control.

The Millers National Federation believes that the milling industry can develop reasonably satisfactory procedures for thiamin control, but naturally it will take time to develop this throughout the entire industry. There are now at least two rapid methods for determining thiamin in addition to the more time-consuming animal assays. Undoubtedly the industry will use the rapid methods in its control work.

1757 I wish also to refer to the laboratory problems affecting others of the ingredients proposed.

At this time it appears difficult to set up laboratory procedures for riboflavin, and impossible to set up such procedures for testing nicotinic acid on an industry-wide basis. There are at least two methods now being studied and in practical use to some extent for determining riboflavin. These are much more rapid than animal assays. It is believed that out of these collaborative studies, at least one reasonably satisfactory method would be obtained which will be superior in point of accuracy and speed to animal assays for riboflavin. The most promising of

these rapid methods, however, is much more time-consuming, and expensive, than the rapid methods for testing thiamin. Some mills are now prepared to make riboflavin determinations. Others can and likely will equip their laboratories and prepare themselves to produce flours for which riboflavin claims will be made. However, if riboflavin should be made a required ingredient at this time it will doubtless be a hardship on smaller mills that do not have available the same facilities for control of this vitamin in the finished product.

Furthermore, the experimental error in the riboflavin determination is much larger than in the thiamin determination. This will result of necessity of using larger
1758 safety factors in the manufacture of flour with added riboflavin, to insure uniform conformity with label declarations. There are no methods available now for laboratory determination of nicotinic acid. There is a recognized nutritional need for nicotinic acid as well as for riboflavin and thiamin. The nation-wide need for added nicotinic acid may be controversial. It need in certain sections where pellagra is prevalent is beyond dispute.

Both riboflavin and nicotinic acid are being added to flour singly or in combination, in limited commercial production. The standard for flour should be so drafted that such production would not be prevented. The manufacturing and laboratory problems relating to the proposed ingredients, calcium and iron, are somewhat different from the vitamin problems. Suitable calcium compounds are available in quantity. Millers are familiar with methods for adding such chemical compounds, and in fact calcium compounds are now being and for many years have been added to flours in regular commercial production.

There are suitable laboratory methods for testing flours for calcium content, but the calcium determination is not as simple or as inexpensive as several of the routine de-
terminations now regularly made in mill labora-
1759 tories, and naturally this determination as well as others required under such standards will add to the expense of laboratory control.

Because of present commercial addition of calcium compounds to flour, it is necessary that calcium be permitted under the new standard. Nutritionists are all agreed regarding this necessity of calcium in the diet. Many are in agreement regarding the desirability of having calcium sup-

plied by several common foods. There may not be entire agreement regarding the desirability of raising the calcium content of flour. It is regarded favorably, however, by those who contend that calcium should be present in flour, at least in amounts sufficient to balance the phosphorus naturally present in flour. Others contend that flour is an ideal carrier for calcium, and that such addition provides a simple, convenient, and economical way to raise the calcium in-take of a large portion of the American public, particularly those who do not consume regularly other common foods that would supply significant amounts of calcium.

As already mentioned, flour is now being manufactured with added calcium compounds for which nutritive claims are justifiably being made. In view of this situation, the Millers National Federation believes that the new definition should include permission to add calcium to this flour.

1760 Perhaps I should refer at this point also to the statements in the record, at the first portion of this hearing in September, to the effect that the British Government has required British millers to add calcium to all flours manufactured in England. This shows the attitude of British nutritionists and confirms the views of American nutritionists who contend that calcium content of the average American diet should be raised and that flour is a suitable carrier of calcium compounds.

Referring now to additions of iron to flour, it may be stated that there are suitable laboratory methods for determining iron in flour. Because of the minute quantities involved, this determination may be classed as a microdetermination. Nevertheless it is an operation which can be conducted by a trained chemist, with the proper equipment, and chemicals. It is believed that millers can adjust their manufacturing operations to the addition of iron compounds. The manufacturing problem is similar to that confronting the industry in the case of calcium additions. Apparently the principal problems to be solved are first the selection of suitable iron compounds, which will be acceptable in the making of bread; and second the production of these iron compounds in sufficient quantity for industry-wide production of flour to which iron will
1761 be added. There is at present uncertainty concerning the acceptability of certain iron compounds now available in quantity, and uncertainty regarding large-

scale production of other compounds of iron which appear to be suitable.

By Mr. Thode:

Q. Dr. Sherwood, because of the character of the determinations involved in the case of certain of these vitamins, in your opinion is it necessary that fair and reasonable tolerances of enforcement must be considered in dealing with this question?

A. Yes, I think it is necessary.

Q. Take for instance the case of nicotinic acid, and the fact that the proposals as we have heard them have suggested maximum limitations, if the miller wished to provide the most nutritive flour possible within this range, how would he actually go about it as a mechanical problem?

A. Since there is no method available to determine rapidly without using a long-extended biological method which is not practicable for this purpose, there would not be any way of determining how much nicotinic acid there is in various types of flour now milled, either short or long extraction, and I presume the only procedure that could be resorted to would be to feed a definite quantity of nicotinic acid and feed sufficient so that the amount added 1762 would conform with the claims made for the product.

Q. Then it would be possible, would it not, that the amount added plus the amount naturally present in the flour might accidentally exceed the maximum specification?

A. It would be quite possible.

Q. Have you any idea of the costs of equipping a laboratory, starting from scratch, to make the determinations that would be involved in a broad definition such as we have used?

A. I have not attempted to calculate that. Ordinarily, we won't start making determinations of this kind—he uses equipment that he has available, buys additional equipment as required, and I have not attempted to calculate what it would cost to equip a laboratory for this particular purpose.

Q. Do you know what the cost of the equipment would be, for instance, to make accurate determinations in the case of thiamin and riboflavin?

A. Yes, I have a fair estimate of what equipment is required for those two particular determinations because we have in our laboratory purchased such equipment.

Q. What was that cost?

A. We have estimated that if you purchase all of the equipment that you need for the thiamin determina-
1763 tion by the Cerecedo & Hennessy method, that it would take somewhere in the range of $1,000 to get the equipment.

Q. How about the equipment necessary for riboflavin determination?

A. We have been using the Snell & Strong, micro-biological method, in our laboratory for making this determination, and I believe that we estimated to equip a laboratory, assuming that none of this equipment was available, it would be somewhere in the range of $2,400.

Q. This equipment I presume would have to be operated by trained personnel?

A. Yes, in both cases. The thiamin determination can be made by any competent analytical chemist, naturally he would have to be trained to make the determination. It is somewhat unusual, but not extremely difficult, and not impossible at all. I would be willing to take any graduate chemist and train him to make the determination.

In the case of the micro-biological determination it seems very desirable and perhaps essential to have someone trained in bacteriology, because the determination is such that the type of training insures more accurate results. A trained chemist who had not had a great deal of bacteriology probably could be adapted to that work all right.

Q. Doctor, in these tests, what are the variables
1764 as you have found them in your determinations?

A. Well, the first variable in any determination, of course, is the ability to secure representative samples. I don't know that the situation is a great deal different in the case of these materials than it is in the case of other flour tests but it is very important, particularly if one is dealing with samples prepared by blending or feeding operations. A fairly large sample of flour should be obtained, if one wishes to test for uniformity, and presence of such added ingredients, to insure that the sample is representative, and according to the usual procedure, that should be quartered down to the small size that one wishes to use for analysis.

Then there are always variables due to what is classed as experimental error in making any determination. Those variables are inherent in the determination itself. In spite

of best efforts to devise a procedure for accurate determination of any component of such material as we are discussing, there are limitations due to the method itself and due to the equipment which is used for making the determination. Those variables to which I refer are not necessarily the same with different determinations, they are able to make some determinations more accurately, and we are able to make replica determinations which agree more closely than in the case of other determi-
1765 nations. To be specific, we have found that thiamin can be determined more accurately, determinations agree more closely, when the same sample is repeatedly tested, than in the case of riboflavin. The micro-biological method has a larger percentage of experimental error.

Q. Doctor, conceding all of these questions of sampling and experimental error, are there actually variations between replicate tests on the same type of sample, and if so what is the percentage of these in your estimation?

A. You are referring to replicate determinations on samples taken during the course of manufacture at different intervals of time?

Q. Well, state that, if you will, first.

A. Well, there is always likely to be some variation in the efficiency with which materials such as flour are produced, while the ultimate goal is absolutely uniform, such as an ideal that can not be obtained perfectly; blending operations due to the variability in natural wheat components, some variability due to feeding operations on a commercial scale will result in measurable differences in some of the components at different periods of time. This, I think, is particularly true in the case of some of the longer extraction flours, where the best system of milling still does not result in producing individual streams
1766 that are always the same, from day to day and month to month. Those factors are out of the control of the millgr., such variabilities are known to exist and they are controlled in the best way possible.

Q. Suppose that you were to take two samples simultaneously out of one mill stream, and test them both, what percentage variation might you get as a result of the character of the determination?

A. Well, do you want me to refer to specific determinations, since it differs, that is probably the only way I can answer it, as to two samples.

Q. On riboflavin?

A. Two samples taken out simultaneously would be assumed to be practically the same in character, and the problem would be one of variability in determination itself. We find in our experience that the thycrome determination of thiamin has a variability which we believe at present should be stated as the order of plus or minus 10 per cent or plus or minus 15 per cent, although practically we can replicate tests within plus or minus 5 per cent. In our laboratory we have not attempted to determine that error statistically. It is possible that at some time that will be done by some chemist, and such report will be made.

Q. What about the same kind of tests conducted
1767 in the case of riboflavin?

A. In the case of riboflavin, the variability undoubtedly is much larger. I think plus or minus 20 per cent, possibly 25 per cent, would come closer, with the type of method that we have been using. We are hoping for some improvement in that method. There are collaborative studies going on with this and other methods at the present time. Some of these studies were reported at the recent meeting of the Association of Official Agricultural Chemists, here in Washington, and those published reports have not come out.

I might remark that I am not familiar with what was reported at that time because I was attending the dietary hearing and was not able to attend those hearings and hear the report so I don't know the report of progress at that particular meeting.

Q. It was time well spent, wasn't it, Doctor?

A. I guess it was.

Q. There has been considerable comment on the part of nutritionists that riboflavin was nutritionally desirable but because of the lack of availability of supply, perhaps the inclusion of it might be deferred until such time as we were assured of a source of supply. Now, do you know, Doctor, whether any progress is being made in that direction?

A. Yes, I know that riboflavin in the form of con-
1768 centrate, and as pure riboflavin, is available. I have been informed that there is a fairly ample supply available to take care of a rather large production of flour. To what extent it would be available promptly for nation-wide distribution of such flour, I can't say, but I think the question of availability is one which should be

looked into by the manufacturers, as shown by the manufacturers of such products.

Mr. Goodrich: Of the riboflavin concentrates, rather than the flour manufacturers?

The Witness: I mean the riboflavin concentrates, when I say such manufacturers, I mean riboflavin concentrates and pure riboflavin.

By Mr. Thode:

Q. Have you any information with respect to the action of the ordinary bleaching agents as proposed in the definition for flour, on thiamin stability?

A. Yes, there is no measurable effect of the ordinary bleaching agents on thiamin.

Q. You have conducted tests which have satisfied you on that point?

A. Yes, we have tested flours unbleached and after bleaching, for thiamin content, and we can find that there is not measurable effect, or we can find no measurable effect upon the content of thiamin, due to the normal 1769 bleaching operations.

Q. Do you have any knowledge of the action of potassium bromate on these vitamins and minerals?

A. Yes, there is no effect that we have been able to detect of potassium bromate in the dough with respect to thiamin and riboflavin content. We baked bread both with and without potassium bromate and we can't see any measurable difference in the thiamin and riboflavin content that could be attributed to the bromate addition.

Mr. Thode: That is all, sir.

Cross-Examination by Mr. Goodrich.

Q. Doctor, in discussing the several problems of the milling industry, do you have in mind particularly the problems arising from the addition and testing of riboflavin added by a selection of mill streams rather than added in the form of pure thiamin hydrochloride?

A. Well, when it comes to the problems of laboratory testing, it is immaterial what the source of riboflavin is. The same variability in the riboflavin determination exists, whether the product of testing is made in one way or another.

Q. The same control problems would not exist, however, would they, if you were adding the riboflavin or thiamin

to the mill stream in the form of concentrates
1770 or in pure form, as you would have in testing the mill streams?

A. Well, you would have a somewhat different type of problem, if feeding operations can be controlled accurately enough, you have an added guide to your control by keeping records of the amount that is fed in. You have that control, in addition to your testing procedure. As I said before, when you come to make the final test you have the variability inherent in the determination and you have the variability of the content of both thiamin and riboflavin in the natural flour, and the mill streams in which you are working. That variability in flours and in mill streams is greater in the case of thiamin than in the case of riboflavin because the thiamin is not as evenly distributed throughout the kernel as the riboflavin is.

Q. The difficulties which you have suggested on testing of thiamin and riboflavin are peculiar to your type of manufacture where you are milling back into the flour streams high in those vitamins, are they not, your problems?

A. No, I would not say that they are just peculiar to that type of operation. I think that these laboratory problems apply to all operations, whether the thiamin is fed back into the flour in the form of mill streams which are rich, or whether it is fed in the form of thiamin
1771 hydrochloride, you still have a feeding problem. If thiamin chloride is fed, it can't be fed in the pure form. The quantity to be fed would be too minute to provide for actual control. Probably it would have to be blended with some other ingredient and then that other ingredient fed in and so then you have two blending operations which must be kept under control.

In case of the feeding in mill streams, you have the variability of the streams, if you are in a position to remove certain mill streams, and test them, and feed them back according to their composition, that facilitates the operation somewhat, and if you are depending on the blending of streams, as the mill operates, then you have some variability that exists in the streams.

The way to overcome some of this practical difficulty, of course, is to allow a safety factor so that the final product conforms to the label declaration that you wish to make. The testing problem, as I have described it, the laboratory control problem, is not so different as I see it,

regardless of the method of manufacture. You still have to put these final products through the testing procedure to make sure that the label declarations are truthful.

Q. Is there a substantial loss of thiamin chloride added in the synthetic form to flour?

1772 A. You mean, mechanical loss?

Q. Mechanical loss by oxidation or anything else, from the time it is added until it comes out for manufacture, or distribution?

A. I would say that there would be no appreciable loss of thiamin, certainly not due to oxidation. It is not readily oxidized. Distributed in flour, it is very stable. There would be no more than a small mechanical loss due to feeding operations. I would not regard that as very significant. Careful operations would have to be conducted, of course, to conserve the thiamin, as an expensive ingredient, and it would have to be handled carefully, but I would not anticipate measurable losses, certainly not during storage of the flour.

Q. Is there a problem of distributing the thiamin chloride throughout the entire batch of flour to which it is added?

A. Yes, I think that there probably is a problem of getting even distribution. That is true in the case of all feeding operations. I believe that the millers are experienced enough with feeding operations to be able to handle that problem, some of them who have not been using self-rising agents, for example, or have not happened to use bleaching agents which are fed in the dry form, might

1773 possibly not have had much experience in such feeding manipulations, but there is no great difficulty in equipping themselves to do that. Careful control in feeding operations should permit a reasonably accurate job of feeding.

Q. There is no real problem of testing the thiamin in the concentrated form, or in the pure form, is there?

A. I would say that there is no real problem in testing the pure thiamin which is purchased. As a matter of fact, pure crystalline thiamin is used as the control measure in the thiamin determination, when one makes a determination of the thiamin content of a known material, he would use thiamin as a control, so I don't regard testing pure thiamin as being a problem at all. We must rely, I believe, pretty largely on the manufacturers of thiamin to deliver us pure chemicals. If the pure thiamin is blended with flour, or some other agent, to permit easier distribution

in the flour stream, then of course that blend must be accurately made, and it would depend on the extent to which each individual mill wants to make such determinations, as to whether they would want to test that.

I would think that that would be very desirable, after it is blended, to make a test, to be sure that there has been no accidental variation.

Q. After blending, tests are not made to determine the amount of bromates added, going into the flour
1774 streams, are they?

A. I believe the usual tests as made to determine the quantity of bromate added during manufacturing, are the baking tests, to see whether desirable baking effects are obtained when the additions are being made. It is not so important to determine the accurate amount, because no claims are being made, ordinarily, for the actual amount of bromate that is being added. It is added in an amount which will bring a desirable baking improvement, and the measure therefore is the extent of that baking improvement.

Of course, there is control of the feeding operation to determine that it is being fed in uniformly and regularly and in the proper amount.

Q. There being definite information as to the purity and potency of thiamin and there being no measurable loss of thiamin when added to the flour, the problem of control of thiamin is no different from the problem of control of potassium bromate or benzoyl peroxide added for bleaching purposes, is it?

A. I don't believe that I can agree with you, Mr. Goodrich, on that. Both of these agents that you have compared with thiamin, benzoyl peroxide and potassium bromate are added to bring about an effect upon the flour, either a
bleaching effect, as in the case of benzoyl peroxide,
1775 which is measured in terms of color improvement, not in terms of quantitative amount of benzoyl peroxide in the flour, because that is changed in its form as it reacts with the coloring matter; the measurement is the effect upon the color, and that measurement is made, and that is the control that is used to see whether the proper amount is added, that is, as well as a check on the amount which is used.

In the case of the bromate, as I have mentioned, the desirable effect of bromate is registered in the baking operations. The way to measure that is to make a baking test,

rather than to determine the quantitative presence of potassium bromate, so that I would not regard the situation as exactly comparable. Furthermore, label declarations on flour to which thiamin or any of these other nutrients are added, must be checked to see that the flour actually conforms with these declarations. In other words, if any miller adds thiamin and makes a guarantee upon his label that he has a certain amount of thiamin in the flour it is only reasonable to expect that periodically he is going to check that finished product to find out if the thiamin is there.

Q. You would not expect a margin of error plus or minus 10 per cent where you were adding the thiamin in the pure form, or in the form of concentrate, which
1776 you could regulate, that you would have in your problem of adding thiamin by a selection of mill streams and then testing rigidly without advance information as to the amount of thiamin actually added into the flour, would you?

A. Well, it is a little difficult to give a categorical answer to that kind of a question, because the efficiency of the feeding and blending operation will, of course, depend in part upon the particular equipment that you have, but I think that we would do pretty well if we feed thiamin in and to control it in plus or minus 10 per cent. Certainly you can't control it within a very small per cent, because commercial operations, in manufacturing, will not permit of the feeding of the amount which you calculate you are going to feed. You have a margin of experimental error in the feeding operation, and just what that margin is I am not prepared to state. It would depend on the feeding equipment, and the control which you could give over it; the flour stream, to which you feed, or to which you add thiamin, is not an absolute constant, in spite of the fact that in mill operations there is a calculated rate of feeding tempered wheat to the first brake roll. There is a variability in that, because there is large-scale equipment, involved, and because we can not control it accurately, and at a uniform level, the amount of wheat that is fed into the mill.
1777 Then as the wheat is ground into flour there are influences which affect the rate of flow, in the different streams, so that the flour streams to which you add thiamin or any other medium, is not an absolute constant quantity. That induces another variable which of course must be taken into account in controlling this operation, so you see that you have a variability due to the efficiency of a feeder,

and you have a variability due to the rate of flow of the flour to which that material is being fed, and those effects may be compensating or they may not be. Consequently there is a possibility there of not absolute uniformity.

I believe that millers can control this so that it is not going to be a particularly difficult operation; I think it can be controlled; but I believe in regulations over the operations there should be tolerances allowed which take into account the experimental error in actually producing the flour. We already have variabilities of the same nature in respect to other factors which we declare for flour, say protein content, ash content, and so forth.

(Discussion off record.)

The Witness: Mr. Goodrich, I would like to expand that last comment of mine just a little to emphasize again what I stated, and to some extent inferred in my direct
1778 testimony. While I have referred to these problems of manufacture and control and laboratory testing, I have tried to indicate not that this operation, that the milling industry could not do it, I have referred to these to show that the milling industry has a problem confronting it to prepare these flours to their satisfaction, and provide products which will be uniformly acceptable, and meet the standards that are being set up. I don't want it inferred that, from my remarks reflecting these difficulties that I have described, that this is an impossible situation, or one which the millers are not going to strive hard to meet, and I think it can be met, but there are adjustments which have to be made in our operations, they are determinations which we have not been making; laboratory operations in the flour mill have been set up for many years on what we might describe as a routine basis. Our chemists and our millers are familiar with the determinations, and their interpretations that we have been making for many years, and now something comes along which is a little new, and it will take some time to make an adjustment to fit this into the milling scheme, but I am confident it can be done, and our concern is a little bit this time over the difficulty in doing this on a nation-wide scale.

We are well aware that certain of the mills which
1779 have been working along these lines, and which have more laboratory facilities than some of the smaller mills, will be able to do this a little more promptly, and a little more easily, than some of the others, but the Federation believes, and we all believe, that this new type of

flour should be made available on a nation-wide scale, and that we should have the entire industry cooperative and prepared to produce these flours and we want to give an opportunity, and I suggest that these things can't be done promptly; we want to give an opportunity for the smaller plants to get themselves prepared so that these flours can be offered.

Q. Your testimony relates primarily to administrative tolerance in allowing deviations from the minimum and maximum levels which have been suggested here by the nutritionists, rather than to a variation of those levels in the standards?

A. Well, I was not intending to imply that I wished to see these minimum levels varied on account of tolerances. I think all regulatory officials appreciate that tolerances in making determinations are always involved.

Q. And that is the point which you wish to bring out at this time?

A. I wish to point out that these tolerances must be considered. We recognize that no figures, no percentages of tolerances will be attached as such; that has not
1780 been the custom, at least in the past, in regulatory work and I am sure that the regulatory chemists are appreciative of this but I wanted to be sure that the record showed that we are appreciative of the necessity of a certain measure of tolerance.

Q. You agree with the minimum and maximum levels which have been suggested by the nutritionists who testified yesterday?

A. Essentially, yes. I am not in disagreement with these minimum and maximum levels. I think that maybe in the case of the maximum levels of the vitamins, that it would be well if they were somewhat higher to permit control of products within those ranges without difficulty, and I realize that when the nutritionists were talking about the maximum levels they were thinking in terms of nutritional effect, and they set minimum levels which I believe that they assumed were rational and reasonable, and then they said that if there is 50 per cent more than that, that should be a maximum level from the nutritional standpoint. Possibly sometimes in manufacturing operations that would not be a desirable maximum, and if manufacturers exceeded that maximum level, in some of their operations, there should be no penalty attached to that for exceeding it. Obviously no manufacturer is going to start

deliberately exceeding these maximum levels. We in
1781 the milling business I am sure all agree that we do not want to see maximum levels raised to a high factor, so that flours with wide spreads of vitamin content in that respect would be made. Nevertheless we do feel that the maximum level should not be set too close to the minimum, so that unavoidably in manufacturing operations a miller might not exceed this maximum level.

Q. Can you suggest a different maximum and give the reasons for your suggestion, on these several vitamins?

A. Well, first let me say in reference to the minerals, I believe it was testified that four times the minimum was suggested as a reasonable maximum, that is in the case of iron. I believe figures were not set for calcium.

That seems reasonable, and I would think from my own personal view, and I don't know whether this is an industry view, because there has been no opportunity to poll the members of the industry, but I would think a maximum level of three or four times the minimum would be better than a maximum level of two times. I doubt that there will be very many cases when products would approach that maximum, but there might be times when, as I have described in the case of nicotinic acid, when without our knowledge we might be exceeding that maximum, if we don't know how much nicotinic acid there is in our
1782 streams, and we can't determine it at present because we have no method, and then if we add a certain amount of nicotinic acid to meet the declaration on the label, it is conceivable from the two sources, the natural streams, and the additions, you might achieve the maximum, but I don't believe it is desirable to raise the maximum figure to very high levels simply to allow somebody to make a product and declare more for it. That is not my view.

Q. I think that that was the reason the nutritionists suggested that a maximum figure be used.

A. That is very sound on their part, I think it is desirable. I think that we do not want to have maxima set so high that there is an opportunity for some unscrupulous manufacturer to put in an unusually large amount, hoping that by making extra claims he will have an advantage for himself.

On the other hand there may be some desirability of offering products with somewhat more than the minimum declared for special uses, for special dietary uses, you

might say, there might be an advantage in having more than is in the minimum, but there should be a maximum which would prevent any ridiculous additions.

Q. Did you make the statement in answer to Mr. Thode's examination that there was no evidence that the amount of Vitamin added in the mill streams affected the
1783 baking qualities of the resultant flour?

A. Well, I don't believe that that was exactly the statement that I was making. That is a fact, however, as far as I am aware, there is no measurable effect of added thiamin upon baking properties. I don't believe that that is what Mr. Thode's question directed to me was about.

Q. There is no measurable effect?

A. No, except, of course, nutritionally.

Q. The nutritional values would be changed?

A. There is a nutritional effect which we can measure in the finished bread, but if you are referring to the effect upon the fermentation of the dough, I would say that there is no appreciable effect due to the addition of thiamin.

Q. When added by selection of mill streams, is the addition of fiber and ash such that it would have any measurable effect upon the resultant flour?

A. No effect of the ash at all. The amount of ash added is very small, whether it is ash content of the whole wheat or certain of the streams, there is no very large effect. There is some effect if there is some amount of calcium, because that affects the dough. The only effect of the crude fiber would be to an increase in crude fiber content; in adding mill streams, we don't measure increase in the
1784 crude fiber content. In the case of the whole wheat flour, of course there is a measurable increase in crude fiber content and if it is bran that is added to contribute this crude fiber, that is noticeable in the finished loaf, yes, that is true, as far as baking characteristics are concerned, the effects of some of the streams are not due to ash or crude fiber, but those effects are apparently due to some other constituents in the wheat germ.

The effects I am referring to are effects upon dough-handling properties, primarily, and some effects due to the pigments of wheat kernels, of course, as you add certain mill streams which are highly pigmented, naturally those pigments appear in the loaf of bread, and the visual appearance is a little different.

Q. Dr. Sherwood, in your original testimony, you gave some evidence with respect to the stability of thiamin in

connection with ordinary bleaching agents, and in connection with potassum bromate, you also gave some evidence with respect to the stability of riboflavin and potassium bromate. Can you tell us anything about the stability of riboflavin with the bleaching agents? I don't believe that you mentioned riboflavin in the bleaching agents.

A. Well, possibly I did not. As far as I am aware from determinations that we have made, the normal bleaching operation does not affect the riboflavin content of
1785 flour. We have had some determinations made of flour unbleached, and flour bleached. As I recall, we could not detect any difference, and if there is any difference it is well within the experimental error of making the determination. I would not anticipate such an effect.

Q. Do you have any information on the stability of nicotinic acid in flour, which is bleached, and also one to which has been added potassium bromate?

A. No, I have not. We have no method of determining nicotinic acid so we could not make a test of that kind. On theoretical grounds I would say that it probably would not, because nicotinic acid is quite a stable compound, and it is present in what one probably should describe in fairly dilute form, the same as these other vitamins in flour streams, and I would not anticipate any effect of the bleaching operation upon nicotinic acid, but I have no concrete data.

Q. Did you participate in the preparation of the standards, proposed standards, introduced into the evidence by Mr. Hardenbergh at the opening of the hearing under the name "Vimin Flour?"

A. Well, I discussed that to some extent with some of the members of the Millers Federation, yes.

Q. It is suggested in the proposed standard that an optional ingredient be permitted for the addition of
1786 iron to the flour, and I believe the language used is "any assimilable iron salt,"—assimilable iron salt.

A. I don't recall the exact language. Perhaps your are correct.

Q. Could you tell us what would be included in that?

A. Well, I presume that word was included just to show that it would be the intention to use edible compounds of iron, to contribute the iron, and presumably the iron would have to be available or there would be no point in adding the compound. I assume that was the purpose of putting that word in, to show that it was not the intention of the

milling industry to ask for the privilege of introducing iron, let us say, as rusty nails or something of that kind, assuming that we would use acceptable iron compounds which would have nutritive food value.

Q. Do you know whether or not any iron compounds were discussed in the preparation of that proposed standard and if so, what compounds they were?

A. Well, I don't recall that I sat in any discussions where specific iron compounds were discussed. There have been some iron compounds discussed by several witnesses, in the adjourned hearing and in the earlier hearing, and I don't recall what iron compounds were discussed as a basis for Mr. Hardenbergh's statement.

1787 Mr. Goodrich: Thank you very much. That is all.

Presiding Officer Willcox: Are there any further questions of Mr. Sherwood?

Cross-Examination by Dr. Strowd.

Q. I would like to ask a question, Dr. Sherwood. There are commercial laboratories which are capable of making any assays that the mills' laboratories are making, and do work for private mills?

A. Well, if you will qualify your term, Dr. Strowd, "any assays" I can answer that. I would say that there are commercial laboratories that I understand are equipped to make certain of these determinations, and I know of no laboratory equipped to make nicotinic acid determinations. I know that there are laboratories equipped to make thiamin assays.

Q. I mean, accepted types of assays?

A. Yes, I have no doubt that if such laboratories are not equipped to make determinations which may become necessary to the miller, they certainly will equip themselves.

Q. And the vitamin manufacturers are usually large concerns, and they have a lot of equipment, have they not, for controls of their product?

A. Undoubtedly they have.

1788 Q. Now, suppose either the vitamin laboratories, or some intermediary concern, should make a master mix under adequate supervision, and then sell that mix, master mix, to the small miller, don't you think that the mill, particularly those that have had experience in mixing self-rising flour, would be able to make a fairly satisfac-

tory product throught the aid that he got from the commercial laboratories?

A. I think that that is possible, by controlling the vitamin and mineral content, if both are included in this master mix, and by controlling the feeding operations and periodically making tests of the finished product, a system of controls certainly can be set up.

Q. Now, if I understood you correctly, you said a while ago that the B_1 or thiamin, from the milling streams, did not affect the baking qualities of flour?

A. Yes, I made that statement.

Q. What about the carrier of the B_1? What I am trying to get at, I don't think that that information is quite clear, or that you quite understood the question, but the mill, or low grade streams in a flour mill, are the richest in B_1, are they not, excluding germ?

A. Those streams which are classified by the miller as low grade or tailing streams, obtained near the end of the mill, are the richest in thiamin, that is right.

1789 Q. Now, if you enrich the flour through the addition of these B_1 rich flour streams, do you or do you not lower the baking quality of the flour, not through the addition of the B_1 but through the flour in which the B_1 is imbedded, as it were?

A. If you use a measurable amount of these streams near the tail of the mill, of course you affect the baking property of the flour. The question that was directed to me earlier, I understood to be a question of determining whether the addition of thiamin affected the baking quality. It does not affect the baking quality, whether you add it in the mill streams or in pure form, but associated with the thiamin in some of these streams are other components of wheat which do have a measurable effect upon the appearance of the loaf, upon the dough handling properties, and those effects are, of course, in direct proportion to the amount and character of the streams that you add.

Q. Now, just one other question, please, sir. I understood you also to say that a high ash did not necessarily affect baking quality. It is a fact, though, is it not, or is it a fact, that a stream with high ash usually has gluten of low quality?

A. Again that question was directed to me earlier, it was directed to the specific effect of the mineral con-
1790 stitutents in the ash of the flour and as I stated then, in the amounts in which ash occurs in wheat and mill

streams, the effects of the minerals themselves are insignificant, if measurable at all. It is well known, of course, that the longer extraction flours, and those higher ash streams have accompanying the ash other constituents which have an effect upon baking properties.

There is a little difference in the character of the gluten, and a little difference in the enzyme of the product, and a little difference in the outer portion of the wheat kernels, and fractions of them, and fractions of bran, and those components have an effect upon baking properties, dough handling, as well as the properties of the finished bread in proportion to the amount present.

They are, you might express it this way, that the association of these with the other components happens to bring this about, but the ash does not exist in sufficient amount to have any measurable effect.

Q. I was just trying to get that together.

A. I am glad to clarify that for the record, if it was not clear. I understood Mr. Goodrich's question to be directed to the specific effects of thiamin and ash and the crude fiber. Of course crude fiber has an effect upon that dough handling property anyone familiar with baking knows that if a large amount of bran is introduced into a 1791 bread dough, you have a different type of dough, and a different type of bread, and in introducing bran you are introducing measurable amounts of crude fiber.

Redirect Examination by Mr. Thode.

Q. You made the statement in your direct examination, in your direct testimony, that there was a possible error of plus or minus 10 per cent in the thiamin determination, because of the very character of the determination itself, did you not?

A. Yes. I am not sure that everyone will agree with my figure of plus or minus 10 per cent. I am basing that on the experience that I have had in our laboratory, and I have heard other people say that the variation is larger, and others have said that it may be less.

Q. Now, is it not true that that variability, because of the character of the determination, would be true whether or not you were testing for thiamin that had been added through mill stream or thiamin that had been induced in the concentrate?

A. The source of the thiamin in the particular sample is immaterial.

Q. That is still plus or minus 10 per cent?
A. The difficulty of determination still exists.

Presiding Office Willcox: Dr. Sherwood, several
1792 of the witnesses have suggested a spread on some of these elements on nutritional grounds, in the ratio of two to three. I gathered from your testimony that in the case, for instance, of thiamin, that spread would not much more than provide for the margin of error in determination, is that your opinion?

The Witness: No, not exactly that, Mr. Willcox. I think the suggestion would provide for the experimental error in the determination quite amply, but I think it would be desirable to have a somewhat higher maximum because of the possibilities that the actual product would be produced suitable for bread-baking purposes, acceptable to consumers, which might have somewhat higher amounts than these maximums suggested, if only 50 per cent above the minimum is accepted as the maximum, and that would allow for both factors, for variability in production, for variability in natural sources of materials, plus tolerances in the assays.

Presiding Officer Willcox: I did not state my question quite broad enough. What I mean is this:

Suppose that a mill sets out to introduce a given amount of thiamin, the several variables in the situation might result in viariations in particular lots of flour, which would approximate the variation proposed here of 100 to 150 per cent.

1793 The Witness: That might be possible until experience were gained in the operation. Obviously no manufacturer is going to deliberately raise the thiamin level away above the minimum requirement but if one is making a long extraction flour, and was not fully aware of its thiamin content, and to be sure that he did not fall below the minimum standards he added thiamin chloride, it is conceivable until he found out how much he had in the finished flour, he could exceed that 50 per cent average and it would be most unfortunate if a manufacturer were penalized for so doing, when the consumer is benefitted rather than harmed by that extra addition.

Presiding Office Willcox: Have you any suggestion on a range which you feel would allow the manufacturer sufficient scope for actual operations, assuming the testimony of nutritionists, suggesting something in the neighborhood of 50 per cent spread on nutritional grounds?

1794 The Witess: Well, my personal view is that that 50 per cent spread was rather small. I was quite in agreement with the figure proposed by Mr. Nelson in his testimony last September, of four times the minimum as a ceiling figure, because I felt that that would allow manufacturers to go along without any concern over exceeding that, and getting into difficulty with the regulatory officials, and obviously there would be no intention of going above that level.

That would prevent any ridiculous additions that might result in unfair claims, presented to the consumer. That type of differential met with my approval at that time, and I haven't changed my views and possibly somewhat less than that would be acceptable.

Presiding Officer Willcox: Would that apply in your opinion to all of these vitamins and minerals that have been under discussion, or do you want to qualify that?

In some instances the witnesses have suggested four times.

The Witness: I see no objection to that applied uniformly to all of these. I can't see that it would not be in the best interest of the consumer to have such a maximum. Certainly the consumer would be adequately protected against any extravagant claims with such a maximum, and when Dr. Nelson first proposed that, in the hearing
1795 in September, it seemed to me that that was quite rational and I still think so.

Presiding Officer Willcox: That would not prevent one manufacturer from advertising and advertising truthfully that he was adding more of certain of these elements than another manufacturer, whereas I take it that this 50 per cent spread would more or less eliminate that.

The Witness: It would eliminate it to some extent and I don't see any advantage in having the spread between the minimum and maximum wide enough so that any manufacturer who wants to add more than the minimum could not do so. I see that that would be an advantage to the consumer, perhaps, if for special purposes, or for extra quality in the product, that products could be manufactured that exceeded this minimum. This minimum is set up, as I understand it, to prevent anyone from adding insignificant amounts and making claims which would mislead the cosumer into believing that he was obtaining a worthwhile product with nutritive properties and by setting a minimum we prevent that from happening, and the

consumer is therefore protected. He knows that if he buys a flour and it has not less than so much, and at that level it makes a measurable contribution to his diet.

Now, it is conceivable that there would be an advantage at times in marketing products which had somewhat
1796 more. I think that there should be a ceiling limit to prevent a ridiculous addition, by some manufacturer who hoped to gain wide distribution for his product, by having 10 times as much as somebody else, and I think that there should be that protection.

It didn't appear to me that with Dr. Nelson's limit of four times the minimum that there was any danger in that regard at all, and that seemed acceptable to me. My personal viewpoint, I wouldn't object to three times these vitamins.

Presiding Officer Willcox: I didn't want to suggest that it was necessarily undesirable, but I wanted to bring out if it is the fact, the difference in operation between a 50 per cent spread, which I take it would mean that all manufacturers would have to operate on substantially the same levels of these ingredients, and a spread of four times where there could be genuine differences in claims, as between different manufacturers. That is true, is it not, as a matter of fact, in your opinion?

The Witness: Yes. I think that that is quite true. There would not be so much variation; there might be greater uniformity if the minimum is fairly close to the maximum, but I can see no disadvantage, and in fact some advantage to the consumer, in having products offered which do exceed somewhat the minimum levels, for which additional nutritional advantages are claimed, and of
1797 course products must conform with those nutritional advantages, and the label declarations would have to show the amounts of vitamins in there, and the manufacturer would have to support those label declarations, and the statements with respect to the vitamins and minerals present would have to be truthful naturally, and not misleading.

Presiding Officer Willcox: Are there any further questions?

Dr. Lee: I would like to ask one.

Cross-Examination by Dr. Lee.

Q. In the baking of bread from that flour, what losses would you expect in the baking process?

A. Well, our experience in baking bread in the laboratory and to some extent in commercial operation has indicated that the loss of B-1 should not be greater than 10 per cent. It may be somewhat less. There is some loss of thiamin in the portion of the crust, which is subjected to the high temperature during the baking. High temperature in the bread, of course, exists only in the outer crust as you know yourself, Dr. Lee, and the internal portion of the bread is not subject to temperatures exceeding the boiling point of water, and at that point during the baking there doesn't seem to be any measurable loss of B-1,
1798 so the loss is confined largely to the crust, and we have found in numerous experiments that it seems to be of the order of 10 per cent or less.

Presiding Officer Willcox: If there are no further questions, I think that we might take a short recess.

(Short recess.)

1799 Presiding Officer Willcox: Dr. Sherwood wants to make one more statement.

The Witness: I would like to refer, Mr. Willcox, further to your question respecting these maximum limits, to be sure that the record is clear with respect to my views.

I referred to Dr. Nelson's maxima of four times as expressed in September as being acceptable to me. In doing so I was thinking in terms of his B-1 minimum, and his B-1 maximum that would be obtained if we used a factor of four times.

Now, if we apply that to the proposal made by the nutritionists yesterday for vitamin B-1, and I believe also for vitamin B-2, but particularly B-1, the maximum four times would be too large in my opinion. I wouldn't want to see the ceiling set so high, if the Government accepts the proposal of B-1 suggested yesterday.

I think with that type of proposal that probably two times instead of 50 per cent more, or double the minimum, would be quite acceptable; personally it would be to me both in the case of B-1, B-2 and nicotinic acid. With Nelson's lower level I thought it should be a little higher.

Presiding Officer Willcox: Thank you. If there are no further questions, Dr. Sherwood is excused.

1800 (Witness excused.)

Mr. Campbell: I think that I would like to put Mr. Hardenbergh on the stand. Whereupon,

CLARENCE H. HARDENBERGH, was called as a witness by and on behalf of the Millers National Federation, and having been previously duly sworn, was examined and testified as follows:

Direct Examination by Mr. Campbell.

Q. Mr. Hardenbergh, when you testified the opening day of this present hearing, you presented a proposed standard of identity for a special type of flour, which was designated in the proposal as Vitamin flour, and you suggested, or recommended that thiamin chloride should be the only required vitamin or mineral, and listed a number of vitamins, or listed riboflavin and nicotinic acid which you recommended as optional vitamin ingredients, and vitamin D, and also iron and calcium, and you stated that you didn't at that time desire to make any recommendations as to the minimum and maximum levels of the various vitamins and minerals that were listed in your proposal.

You have heard the testimony of Dr. Wilder, and Dr. Sebrell, and Dr. Jolliffe, who, as I understand their testimony, were in agreement among themselves as to the

1801 maximum and minimum levels of these ingredients, and were also in accord with Dr. Nelson's testimony with the exception that in the case of thiamin they recommended a higher minimum level.

Will you please state what recommendations you have to make now, on behalf of the Millers National Federation to fill in these blanks of minimum and maximum quantities in your proposal?

A. We are willing to accept the suggestions that were made by Dr. Wilder, and Dr. Jolliffe, and Dr. Sebrell yesterday, and in odrer to clear the record, this is the way I have it down.

On calcium, I have 492 or 500, and now either one is satisfactory to us. I don't know, really.

492 as a minimum and four times that as a maximum. On iron it is 6.15 milligrams and fours times for maximum.

Q. That is per pound of flour.

A. All of this is per pound of flour, for B-1, 550 International units per pound, and 50 per cent, or 825 for a maximum.

Q. That would be 1.66 milligrams per pound as the minimum?

A. I think that that is the way it figures. I got 550 per pound, and I don't know how that figures back.

1802 Mr. Goodrich: That is International units.

The Witness: Yes.

B-2, 1.22, and 1.23, that is getting down pretty fine. I have got two figures for the bottom limit. That is as a minimum, and the maximum should be limited to 50 per cent of that, or which would be 1.82, or 1.83.

Nicotinic acid is 6.15.

By Mr. Campbell:

Q. That is milligrams?

A. Yes, per pound, and the maximum would be 50 per cent above that figure, and that would be 9.22.

Q. I think 10 is what Dr. Jolliffe gave as his figure.

A. Yes.

Q. But whatever discrepancy there might be in the figures which you have listed, you are willing to accept the figures of those three nutritionists, Dr. Sebrell, Wilder and Jolliffe?

A. Yes. They, as I recall, put no minimum or maximum in connection with vitamin D, and I think that the minimum should be 100 units on the basis of 6¼ ounces of flour. I think that that is right.

Dr. Strowd: One of them did put a minimum of 100.

The Witness: That is acceptable to us on vitamin D.

Mr. Goodrich: That is for 6¼ ounces?

1803 The Witness: Yes.

By Mr. Campbell:

Q. Now, getting to the question of the disparity in the recommendation that you made, that is where you recommended thiamin as the sole required optional ingredient of this list, and the recommendation of the nutritionists that thiamin and nicotinic acid and iron should be required ingredients, and that with the understanding that riboflavin would be a required ingredient at such time as it was commercially available, what have you to suggest on that, as to whether there is any reconcilement of your first position, with the recommendations of the three nutritionists whose names I mentioned.

A. Well, we feel that our first recommendation, that is to have the requirement for B-1 only, was not unreasonable, and we still hold to that idea, not with the idea that we are in any way trying to hinder or block the end which is sought; we are in favor of it.

Dr. Sherwood in his testimony brought out some of the difficulties from a practical point of view, which the milling industry has to face in trying to help make this proposition a success, but we feel that we are going pretty fast in trying to include all of these things, trying to include these three nutrients.

Q. Thiamin, nocibinic acid and iron?

1804 A. Yes, with a required minimum. There are about five thousand mills in the United States, that is, that figure was approximately the number which was recorded in connection with the processing tax law.

Q. The Agricultural Adjustment Act?

A. The processing tax is what I was trying to think of. Now, there are about a thousand mills in the United States, in round figures, that make somewhere around 90 per cent of the total production of the flour, I think. That is one thousand out of five, making 90 per cent so you can see the balance of the remaining mills are pretty small.

Now, there are about 450 mills out of that thousand mills that make somewhere around 80 or 90 per cent of the total production of the country.

Now, the question is, if this thing is up in the immediate future, on the basis that these three nutrients must be required, in order to put out this flour, is it going to play into the hands of a certain group of mills to the detriment of other mills, and even if it did, can the flour be offered throughout the country to the greatest number of people to do the greatest good, by following the proposal of the expert nutritionists that we require these three ingredi-

1805 ents, or can it be better accomplished by following the suggestions of the Federation that to start with, we require thiamin only, in this minimum amount, and then just as fast as the mills can get lined up to perform the task, and the job which they ought to do, to increase these requirements.

That is, take riboflavin, for instance. The nutritionists, I think recognize that perhaps there was not a sufficient quantity to warrant including that nutrient as a required nutrient, so that they said within a year.

Our idea is very much the same. We say start off with thiamin only, and then add these other things. To tell you how crude this proposition is right today, as far as riboflavin is concerned, during the two weeks before we came down here, our company, which is not equipped in our laboratory to make tests for riboflavin, sent out to a laboratory which was supposed to be able to run a test on riboflavin, four samples of flour. One of them was a short patent flour made of southwestern wheat, one a short patent flour made of spring wheat, and one of them was a sample of so-called long extraction flour, which we picked up, and on which there is some business by some of the mill, the other was a long extraction flour which was monkeyed around with in our mills and trying to match it.

1806 The laboratory returned a report to us on those four samples. They found a trace of riboflavin in the spring wheat short patent, a little more of a trace of it in the Kansas short patent, and none in the long extraction flours.

We weren't satisfied, of course, and we sent the samples to another laboratory, and they came back more in line with what we have been led to believe was the correct answer. That is, they found a little in the two short patent flours, and they found considerably more in the long extraction flours, which is the way it ought to be.

But I am just showing you how crude this proposition is today, with the laboratories, and the methods that we have for analyzing. We had to send these samples out. We have no way to test them, and now we can get a way. We are going to get a way, but we are a relatively large milling company. I simply want to bring some of these things out, because it is all in the interest of what we are trying to do.

As I said, don't think that we are trying to block this thing by this information we are putting in. We are not.

Q. Your testimony now is on behalf of the industry as a whole, and not on behalf of Commander Larrabee Company?

1807 A. Absolutely; we will go to it 100 per cent, but I am talking about the entire milling industry and what is the best way to approach it. It isn't going to take very long. If you will require start in and say, vitamin B-1, and you find out how fast riboflavin can be made within the next year, and you find out how fast improved

methods of testing for riboflavin can be made, and find some way to test nicotinic acid, and just as soon as you find these out, call us and say we want to change these requirements, and we will be right down here.

We aren't going to make any objections to them. We will go right along with them.

Q. Mr. Hardenbergh, to bring you back into the stream, Dr. Wilder testified at the hearing yesterday that he estimated that the cost of these added nutrients as I understand it—he was referring to the ones that were recommended as requirements by him—would figure somewhere between 35 cents and 75 cents per barrel, and on cross examination he said that he had not included in his estimate the cost of feeding in and control.

Now, have you something that you would like to say on that subject?

A. The actual cost of feeding in is negligible. The cost of control was brought out by Dr. Sherwood. The cost of equipment and the cost of the proper personnel in 1808 order to make these tests, would be pretty near the same for a very small mill if they wanted to do it themselves as it would be for a large mill, and the cost per barrel is going to depend entirely upon how much flour is put out. If a considerable amount of flour is produced by a large mill the capital investment, or even the actual cost of the personnel to run it, from day to day, which would be a continuous cost would be small. For a small mill it would be relatively large. If the small mill has to have all of its work done outside, it would amount to a considerable item for that mill.

Right there I would like to say something in regard to this idea of a master chemical.

Q. That is what Dr. Strowd referred to as a master mix?

A. Yes. The idea, which I might say even some of the nutritionists with whom I had talked, was advanced that all that you have to do in order to get these three things into flour is to buy from the chemical company a product which has these three chemicals mixed together, then add it to the flour and then test the flour for iron. If the flour has the correct amount of iron in it, why, you will naturally assume that the other chemicals must be in there in so far as the feed-in goes, providing we got the right 1809 chemical from the chemical company to begin with.

Do you get the idea?

This would be difficult from the practical point of view except for the very small mills. We will take a small mill first, who runs a batch feeder, and who only put out one grade of flour. They can send their sample of flour out, their one grade that they want to make, and they can have it analyzed then they can go to the chemical company and say that they want a master mix, that is, rather simple for them in small sized mill.

Now, you take a larger mill, the mills which will make an effort, probably, to put on the market some of these longer extractions flours, in which the natural nutrients are increased, by the use of the low grade streams. The mixture which they have would have to add to a long extraction flour would be an entirely different mix than they would add to a short patent. You would be all up and down the line. If the same mill, is grinding two or three different wheat mixes, for different classes of trade, it would have to use another bunch of mixtures. That is, this idea of simply getting one mix, and that is all there is to it isn't practical. You have got to have a mix for every grade of flour, unless you want to get a mix strong enough to take care of the poorest, and then put it
1810 in where it isn't needed, in which case you are unduly raising the price of something which might have some natural ingredients in it.

It isn't just simply getting one powder and that is all there is to it, and just feeding it in. A mill of any size, if they want to keep their prices down, would have to get the amount of all of these different elements in all of the different flours that they make, different grade and from different wheats and so forth, and then feed them in separately to get the right amount of each one in.

Q. I take it from what you have just said that it would be impossible for you to cite any definite figure as to the combined cost of the ingredients, and the feeding in and control of this product, in terms of a barrel of flour.

A. It would be impossible, because as I say, we know that the actual cost of feeding in is only anywhere from two to perhaps six cents a barrel at a maximum.

We have no way of determining on a per barrel basis what the cost of the laboratory equipment and the running of the tests and so forth is, because it depends entirely upon your capital investment against the production of your flour, and nobody knows what that would be, and we make no estimate of it.

1811 We have talked this over quite a little among ourselves and while we can make no statement in regard to the actual price effect to the ultimate consumer, we do believe that the increased price would not stop or prevent the accomplishment of the end sought.

Q. And you would be in favor of risking the additional cost element in order to go ahead with this nutritional program, is that right?

A. Yes.

Q. Now, Mr. Hardenbergh, in order to attempt to get some order out of chaos in the former hearing, and this hearing, with respect to the recommendations of the Millers National Federation, as to optional ingredients, it is my understanding, and you can correct me if I am in error, that on behalf of the Federation at the September hearing, it was recommended that the following optional ingredients be allowed in connection with the standard of identity under Section 15.000, the calcium compounds, vitamin B-1, thiamin chloride, nicotinic acid, processed wheat germ, vitamin B-1, riboflavin, iron compounds, and vitamin D.

It was also suggested at that time that vitamins A and C had not been in commercial use, but were in the stage of research. Now, will you please state what the views and recommendations of the Millers National Federation are with respect to these optional ingredients recom-

1812 mended at the previous hearing, in view of the proceedings that have taken place at this November hearing?

A. To be technically correct, I presume that the calcium compound should be changed to calcium. That is, we are not asking for broad calcium compounds as optional ingredients. We list these optional ingredients that we have talked about, the metal calcium, and this reads calcium compounds, you see, and what we want to include is calcium, that is the high calcium compounds necessarily, some one might not know what we mean by calcium compounds. We mean calcium.

We want to eliminate, and have no desire to include or keep this list vitamin C and vitamin A. In connection with our request for processed wheat germ, that was subdivided into dehydrated wheat germ and defatted wheat germ and wheat germ oil, and we want to eliminate wheat germ oil.

What I said in regard to calcium compounds would apply too, in a very technical point of view, to iron compounds,

and we know that we have got to get the iron in which is in the form of compound, but what we are asking for in the form of nutrients is iron.

We are in a predicament in regard to these optional ingredients.

Q. You also wanted vitamin D?

1813 A. Yes. I thought that that was in the list, vitamin D was in the list. The only thing that we are taking out of the list is vitamin A and C, and processed wheat germ oil.

Q. Before you get to that, when I asked you this question about optional ingredients, section 15.000, I was only referring to the optional ingredients requested which would be classed as minerals and vitamins, and I didn't refer to, for instance, potassium bromate, and malted barley flour, in connection with adding it to compensate for deficiency in enzymes, I was relating it purely to vitamins and minerals.

A. Yes, because those were the nutrients, or elements or products in connection with which the hearing was postponed until this date.

Q. That is right.

A. As I stated, we are in a quandary in regard to these nutrients in connection with the standard of identity as set up for 15.000, in connection with which we ask that these be considered optional ingredients.

We do not want to withdraw our request that they be considered optional ingredients, because this proposition of trying to make flours as nutritive as possible on as broad a scale as possible, to do the greatest good to the greatest number of people, must be left on a broad basis,

1814 and as Dr. Sebrell and Dr. Wilder both testified, we should not find ourselves in a position where we can not make a flour between a flour which has none of these vitamins in it, and a flour which is like this Vimin flour which is going to require definitely and specifically in the end a certain number of these vitamins must be in it.

In other words, if a baker comes to a mill and says, "We want to make our bread with certain vitamins in it, but we want to put our thiamin in by the yeast method; we would like to have you make us a flour which has nicotinic acid and iron and perhaps riboflavin in it, at some future date," the mill should be able to make that so-called prescription flour, likewise.

We can conceive easily from some of the statements

that were made by one of the representatives of the Government at a meeting that was held at Chicago, that the requisition departments of the Government for the Army or Navy or some other institutions might want bids for flour which contained perhaps thiamin only, and perhaps they might not want all of these other ingredients in them, because when you come to requisitioning for people in institutions, or even our Army, that is what the boys get to eat, or what these people get to eat, they are able to control their rationing to a good deal better extent than the man in the street. He eats what he wants.

1815 In other words, we can't tie this thing down, as we see it, and simply have a standard of identity for plain flour, and say that to that plain flour we can add none of these nutrients even as optional ingredients.

And then have against that a standard of identity for Vimin flour which requires, starting out with thiamin only, but looking ahead which is going to require three or four of these nutritive elements required in specific amounts, and then have nothing in between. That is going to defeat part of the purpose as we believe it of this whole nutritional end sought.

Now, whether to ask for these nutrient ingredients as optional ingredients for white flour, plain flour, flour, wheat flour, or whether to suggest another standard of identity which would include any one or all of these ingredients as optional ingredients with the proper labeling, frankly we don't know what is the best way of approach because we do not know, and we have no way of knowing how the administration from a legal point of view, and from the administrative point of view of this law, is going to view this thing, and all we can do is to present now the proposition which faces us, and let the people who know how they are going to administer the law, and how they want to write these standards of identity, let them so write them so that the industry and the public and this whole

1816 proposition can be properly protected.

Q. Dr. Sherwood in his testimony suggested that the maximum levels of these nutrients, or some of the nutrients as recommended by Dr. Sebrell and Wilder and Jolliffe were too low.

Now, you have stated that you have agreed with the levels which were recommended by these three nutritionists. Now, as to the maximum levels suggested by Dr. Sherwood, where they differed from the maximum levels sug-

gested by the nutritionists, which of the two recommendations do you favor for adequate control purposes?

A. I am not sure whether I can remember as to just exactly what was the difference on thiamin chloride and riboflavin only; were those the two differences?

Q. As I understand Dr. Sherwood's testimony, and he can correct me if I misstate him, he recommended a maximum level of thiamin at twice the minimum level, and that the nutritionists recommended the maximum to be 50 per cent greater than the minimum, is that right, for control purposes?

A. Well, I thought that we would get by with 50 per cent more, if you start in with 550. We know that if we want that amount in, in our product, we have probably got to go to over 600. That is because you have got a full variation of 10 or 15 per cent. That is, if we figured
1817 that we had, say, 600 in there, or even if we went up to 650, we would say that we would have to have 650 because the variation is going to be, say, 15 per cent. That is around 80 units. That would be off of that, and that is going to bring us down to 570, as against this 550.

Now, I don't think we are going to strive for the maximum. I don't see any point of anybody going up to the maximum, but if we got a figure here between 550 and 625, and we know that that is this variation coming in here, we can't put in just 550 in there, according to our records, because then when we put it out and if it is picked out and picked up and the state or the federal government, on account of this variation of 10 per cent they only got 450, and they come to us and they say, "Well, you have got only 450 in there."

In other words, we have got to shoot at something in our mixture above this minimum of 550 in order to insure keeping ourselves out of trouble.

Now, I don't think as far as thiamin goes, and from the information which I have gotten from our laboratory and other laboratories, that a variation probably of 15 per cent would be enough to cover us. Now, if we can go up to 650 or 675, when we put it in, that is this limit of 800 is high enough, and we don't want it away up, because we don't want somebody putting in 1600 units of it.
1818 and making additional claims for stronger thiamin flour,—that is what we are trying to avoid.

Now, when you come to this limit on riboflavin, I don't know. I don't know where the limit should go, and I don't

think anybody else knows, and nicotinic acid, all we are doing is adding something to something that we don't know whether we have got it or not.

And so I couldn't answer that question. I understand that the representatives here of the Commercial Solvent people that make this material, in which there is this riboflavin concentrate. Perhaps they can give you some information in regard to that product, but I do not know enough and haven't enough information to talk about these other maximums, but they must be high enough to take care of the proposition of the mill getting enough over the minimum, and then the variation in the tests, so that it isn't going to throw them into trouble if the test that is made is so erratic that it shows below what they are supposed to have in it.

1820 Mr. Goodrich: I think there is a gentleman here from Commercial Solvents Company who wants to be heard on riboflavin concentrates.

Presiding Officer Willcox: I think this would be an appropriate time to hear him.

Mr. Thode: I would like at this moment to make 1821 one brief motion.

At the last convention of this hearing, in September, General Mills introduced a proposed definition and standard for a new nutritional flour, and supported that definition with considerable testimony.

We feel that we will perhaps have a large measure of the responsibility from the industry standpoint, in carrying forth and presenting any problem involving a new flour which has been made according to nutritional specifications, and I would like therefore to move that the testimony which we introduced in the September meeting of this hearing be made applicable to, and in support of, the testimony of the nutritionists yesterday, in all of its pertinent respects.

Mr. Goodrich: I don't think that these motions are necessary. The evidence is in addition to what was given at the previous hearing, and on the understanding that it would be in addition thereto, and all of the evidence in the record at the previous hearing will be considered in so far as it is pertinent to suggestions which have been made at this hearing.

Presiding Officer Willcox: That is certainly true, and I am inclined to agree that no motion was necessary. I think if Mr. Thode merely means that his testimony was not

limited to the specific proposal, which he presented on
1822 behalf of General Mills at that previous hearing.

Mr. Thode: I am not on the stand to testify, so I made a motion to show our complete accord with the general program, sir.

Presiding Officer Willcox: No formal ruling on the motion is necessary.

I will request you to make a statement on that. Whereupon

O. R. BRUNKOW, was called as a witness by and on behalf of Commercial Solvents Company, and having been first duly sworn, was examined and testified as follows:

Presiding Officer Willcox: Will you please state your name and occupation and representation for the record?

The Witness: O. R. Brunkow, sales manager, Commercial Solvents Corporation, New York City.

Presiding Officer Willcox: Mr. Brunkow, I should like to have in the record any information that you can give in regard to the availability for the purposes here under discussion of riboflavin, either in pure form or in the form of concentrate, or other form suitable for the addition in flour.

The Witness: Well, for some time we have been marketing a product known as Solvomin; that is the trade name for it; that is rich in riboflavin. At the present
1823 time we are offering it at a potency of 4,000 micrograms per gram, and the small plant which is now operating has an annual output sufficient to take care of one million barrels of flour a year.

That production is capable of expansion fairly rapidly so that should the industry require additional amounts, we feel that we can keep pace with what the industry may require.

As far as the incorporation of riboflavin in flour, as to amounts, that certainly is a question for the nutritionists to decide, and we have no recommendations to make on that basis.

Presiding Officer Willcox: Are there any questions?

Cross-Examination by Mr. Goodrich.

Q. Do you have on the market a concentrate of riboflavin at the present time?

A. Yes; except the Food and Drug Administration will not permit the word "concentrate". It is a product rich in riboflavin.

Q. A product rich in riboflavin?

A. Yes.

Q. And Dr. Wilder read into the record yesterday a description of the method of preparing this product.

A. So I understand.

1824 Q. Have you seen the statement which he read, and is that—

A. I have not seen the statement which he read, but I understand it was a statement which we prepared for the American Medical Association, and the Food and Drug Administration, in getting approval for the use of the product. It was entirely satisfactory.

Q. That statement was prepared by your company?

A. Yes, sir.

Mr. Goodrich: Thank you.

Cross-Examination by Mr. Campbell.

Q. Are there any other companies that you know of who are putting out a substance that is rich in riboflavin that could be used for the purpose of enriching flour?

A. I don't know of anything similar. Now, of course you have pure riboflavin crystals made synthetically. It is felt, however, that a natural product such as ours has an advantage as a source of riboflavin because it contains other factors, if that is permissible.

Cross-Examination by Mr. Hardenbergh.

Q. Are you in the chemical end of the business, that is, if we used this product and put it in flour, how about testing to know whether it is in there? Can you give me 1825 any information?

A. We are using in our method of assay—we will use the method of Snell and Strong, which I think is quite acceptable, and that is a bacterial method, and it is very rapid. In forty-eight hours we can give you an assay of the riboflavin content.

Q. When you say bacteria, that isn't this fluorescent method?

A. No, that is entirely a different method.

Q. You say it takes forty-eight hours to get the result?

A. Yes, as compared to the old biological assays, where you used chickens or rats, why, it is very rapid.

Q. How accurate is it?

A. I wouldn't make a statement to that effect. I think Dr. Sherwood would know more about the accuracy of the method.

Q. You don't think it is very accurate?

A. I am unprepared to make a statement as to the accuracy of the method.

Cross-Examination (Continued) by Mr. Goodrich.

Q. Is the process by which this product rich in riboflavin is made a patented process and owned by Commercial Solvents Corporation?

1826 A. Yes.

Mr. Goodrich: Thank you.

(Witness excused.)

Presiding Officer Willcox: Has the Government any testimony to offer on the addition of vitamins and minerals?

Mr. Goodrich: Not right now.

Presiding Officer Willcox: You don't mean to foreclose yourself from the end of this hearing?

Mr. Goodrich: No sir.

Presiding Officer Willcox: There are two consumer witnesses who wanted to testify, and one of them asked to be permitted to wait until tomorrow, and I think we might then postpone any consumer testimony until tomorrow, unless there is some consumer who definitely prefers to be heard now.

After the noon recess we will take up the matter of sodium acid pyrophosphate; whether we can finish that this afternoon, now, of course I can't tell.

The other subjects to be taken up are certain additional testimony in regard to whole wheat products and the question of the introduction of magnesium carbonate, and calcium carbonate in self rising flour.

We will reconvene at 1:45.

(Whereupon, at 12:20 o'clock p. m., the hearing was recessed until 1:45 o'clock p. m. the same day.)

1827 Afternoon Session.

(The hearing was reconvened at 1:45 o'clock p. m.)

Presiding Officer Willcox: We will come to order, please. I have an affidavit here, submitted by Mr. Robert S. Harris, who testified in these hearings, in which he makes proposals regarding minima and maxima of certain ingredients, certain nutritive ingredients in flour. Does anyone care to look over this affidavit before it is placed in evidence?

Mr. Goodrich: Mr. [redacted] I suggest that Dr. Harris suggests the same levels on the nutrient as were suggested by Drs. Wilder, Sebrell, and others who testified here, and he has made the same mistake in arithmetic there.

Presiding Officer Willcox: If there is no objection, this will be received and marked as Exhibit "EE" on behalf of the Cream of Wheat Corporation.

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1927 PROCEEDINGS.

Presiding Officer Willcox: We will proceed this morning with some of the consumer witnesses. Whereupon

MADELINE ROSS, assumed the stand as a witness in behalf of the Consumers Union of the United States, and having been duly sworn, testified as follows:

Direct Examination.

Presiding Officer Willcox: Will you please state your name and residence for the record?

The Witness: My name is Madeline Ross, and I represent the Consumers Union of the United States, 17 Union Square West, New York City.

Presiding Officer Willcox: Will you tell us a little about the Consumers Union, and their representation in the course of your statement.

The Witness: I will make that part of my statement. I represent the Consumers Union which is a non-profit technical organization with something over 80,000 members throughout the United States. We are engaged primarily in the testing of consumer commodities, including foods,

drugs and cosmetics. The information which is derived from our tests is published in terms of brand name in-
formation in the monthly publication which we put
1928 out, called the "Cousumers Union Reports", which is
sent to our members. Although the major portion of our work is in the field of testing, we attempt in addition to inform our members of important legislation which may affect them, and in connection with that we try wherever possible to attend such hearings and to represent their interests.

The question has been raised as to what my representation actually means in terms of the opinions of our members. It is of course impossible to make a poll of every member on every point of legislation which is under consideration, but we do from time to time send out questionnaires, asking our members their views on various matters of policy, and our action is of course guided by their replies, as well as by their individual responses to articles which we publish in our reports. I might say that regarding our position on the Food, Drug and Cosmetic Act, I have heard no dissent from our members from the opinions which we have expressed from time to time, and the opinions which I am about to express in this connection are to the best of my knowledge in direct line with that position which has been approved by our members.

As to the character of my testimony, I am speaking simply as a consumer representative, not as a qualified
expert in problems of nutrition. My background is in
1929 this particular field made up of five years work on
the technical staff of the Consumers Union. My work has included among other things, setting up test methods, and interpreting test data on foods, drugs and cosmetics, writing articles in regard to such tests for publication in the reports, making studies on pending legislation, both local and Federal, dealing with foods, drugs and cosmetics, and in a general way gathering and preparing data in these fields for the benefit of our members.

Let me say first that we always have been and still are opposed to the indiscriminate fortification of foods with vitamins and minerals. In most cases we felt that such fortification is not only unnecessary, but to a degree dangerous in that it tends to cause a false sense of security when if is coupled as it so frequently is, with rather dubious advertising claims.

For several reasons, however, we consider flour as an

exception. In the first place white flour as we know it today is far from being the natural product which it was before modern milling methods came into wide useage, and although our normal inclination would be to educate the consumer in the use of whole wheat flour to correct this situation, we realize that the educational process is slow. The ratio of the whole wheat to the white flour in this country is amazingly low, despite many attempts at 1930-39 education, and so we must accept the fact that people are apparently simply preferring the white flour to whole wheat flour.

There has been abundant testimony presented here to the effect that even the good American diet is likely to fall below the optimum level especially in factors of the Vitamin B Complex. The poor diet is frequently well below the minimum for protection. Although it is possible by the inclusion of liberal amounts of protective foods to bring the B_1 content, let us say, of the diet up to minimum requirements it appears difficult, if not impossible, to reach optimal limits and still to include the quantities of white bread, sweets and other refined foods to which people are accustomed.

A number of estimates have been given on the amounts of bread and other forms of flour contained or consumed per person per day in this country, some of them perhaps have seemed a little higher than generally accepted levels, but in any case there is agreement that flour provides very roughly a third of the calories in both low and high income groups.

It is agreed then that fortification of white flour is desirable on several bases; first, that white flour has been deprived of certain vitamins and minerals through modern refining methods. Second, that there is a wide-1940 spread deficiency of some vitamins and minerals in the American diet, particularly among low income groups; and third, that flour contributes a large portion of the caloric in-take among low and high income groups alike.

Then there are two major problems which come up, what factors shall be added to flour and how much shall be added. In answer, we would be inclined to define fortification of flour as the addition of all normal constituents found in the whole wheat flour which is possible commercially to add, in at least the amounts normally present in whole wheat flour.

That is of course, and purposely so, a loose definition containing as it does the phrases "commercially feasible," and at least the major aim of the fortification of flour as we understand it is to bring a better nutrition level especially to the low-income family. This aim is lost as soon as the price of the fortified flour becomes substantially higher than that of ordinary flour.

The data available currently would seem to indicate that Vitamin B_1, nicotinic acid, iron and perhaps calcium could be added without causing substantial price increase. We feel that these should be the required ingredients in a fortified flour. We agree too that a certain number of optional ingredients should be added if desired, namely riboflavin, Vitamin D, and possibly phosphorus. Ribo-
1941 flavin is placed among optional ingredients only to-
day because it is not available today at prices or quantities which would make its addition to flour possible at low cost, but as the demand grows there seems likelihood that methods will be found to make it cheaply and widely available. At such time riboflavin should certainly be placed on the required list.

It is to be hoped that the situation with respect to riboflavin will be analogous with that of thiamin, which too was once rare and expensive. Today it sells at close to a dollar a gram, and can be produced for 50 cents a gram, I am informed. Assuming that the millers may find it well to do their own producing, the proposed 550 International Units per pound would cost less than a tenth of a cent per pound of flour.

Now the quantitative aspect of fortification. We have suggested as a basis at least the levels found in whole wheat. We would certainly not be opposed to the higher levels, particularly of the B complex, which has been suggested here by Doctors Nelson, Wilder, Sebrell and others, that is one-fourth of the day's requirements of the day's vitamins and minerals in six and a half ounces.

But we feel whatever the level decided upon, certain limitations should be placed on the permissible label claims.

In the first place, some sort of standard name
1942 should be adopted and required to be used consistently by all producers. We are inclined to favor the term "fortified" as being properly descriptive and already quite familiar to the consumer.

"Restored" we would feel would be a misnomer because

our present knowledge of the composition of wheat is inadequate to permit actual synthetic restoration of all of the components removed in milling and even if our knowledge were adequate such complete restoration would be incompatible with the production of a cheap fortified flour.

The newly coined term "Vimin" to signify addition of vitamins and minerals is not entirely satisfactory. In the first place, it is a new word which is not currently used in our vocabulary. Such a manufactured term is we feel justified only if there is not already a term in common usage which serves the same purpose. In this case such a term is available.

In addition, if it were permitted to apply the term "Vimin" to a flour fortified with Vitamin B_1 alone as has been proposed, the term would be definitely mis-leading. "Enriched" has been proposed, and that is not especially objectionable although we consider "fortified" as somewhat more descriptive.

A second limitation that we ask is that label claims for fortified flour be strictly limited. No claims should
1943 be permitted which would tend to give users of fortified flour a false sense of security. It is essential if the fortified flour is to fill its purpose of raising the nutritional level that it be not permitted to give to consumers the implication that in using it they may safely neglect the rest of their diet. For this reason we feel that the label statement concerning fortification should be simply a statement that the flour is fortified, plus the fact that it contains in a given amount at least a certain proportion of the day's requirements of the required optional vitamins and minerals which are present, or alternatively if the whole wheat flour is to be considered as a basis, the statement should simply be that the level of certain required and optional ingredients has been raised to the level of whole wheat flour.

We believe that the proportion and given amount referred to above should be fixed in the standard, as for example, I quote "Contains at least one-quarter of the daily requirements of" and then the name of the products inserted "in a six and a half ounce portion."

If this were done, the maxima or ceilings on ingredients which have been proposed would not be essential for the purpose of regulation, since they would presumably be taken care of automatically. That is a miller would not

be penalized for fortifying above the minimum except
1944 perhaps economically. At the same time he could not make possibly misleading claims for his products because it contains fortifying ingredients above the minimum requirement. In effect, such a step would probably serve to keep fortifying ingredients near the minimum. This would seem necessary if flour and the bread made from it are to be kept as foods rather than as vehicles for medication. Any flour which makes further claims than this should, we feel, be properly placed in the category of dietary food and be subject to regulations which are being promulgated for it.

Let me add one more thing, and that is a plea for simplicity in nomenclature of the ingredients and units. We are here all familiar with the fact that Vitamin B_1 is synonymous with thiamin; nicotinic acid with palagra preventing factor, and riboflavin with vitamin B_2, and so forth, and we know, too, that for some vitamins International units, U. S. P. units, Sherman Units, millograms, and micrograms and so forth exist and they can be converted one into another. But the average consumer is in a truly difficult position. He is just beginning to learn one set of names, and tying them up with functions and requirements. All possible efforts should we feel be made to keep his job as easy as possible.

In the hearings on dietary foods held a couple of
1945 weeks ago standard names for the vitamins and minerals as well as preferred expressions of units were proposed. We urge that the final regulation on fortified flour should be based on the same nomenclature.

Cross-Examination by Mr. Goodrich.

Q. You gave us some information with respect to your representation. I would like to have you state for the record the way in which you are authorized to appear and represent the union. Is it by order of the Executive Committee or some other way?

A. Yes, it is by order of the Executive Committee, which is a body elected by the Board of Directors of the Consumers Union, which is in turn elected by the membership.

Q. And in the designation of you as a representative at these hearings, were instructions or any general policy stated which you were to carry out in these hearings?

A. Yes. Before coming down, I had a consultation with Dr. Harold Aron, who is our medical advisor, Dr. William M. Malisoff, who is a bio-chemist, and technical advisor, and the Director of the Consumers Union, Arthur Callett. I was not given specific instruction on every
point, but a general discussion was held in which we
1946 agreed on the general policies to be followed.

Q. You stated that your have had no evidence of membership dissent from the positions which you have taken at the several hearings, and I assume that the Consumers Union members are fully informed of the proceedings which have gone before, and of the questions involved in the several hearings?

A. Yes. We publish brief summaries, not complete reprints, of course, of the statements that have been made, and I might say that the response when there is disagreement is usually pretty prompt, and we have had no such response.

Q. And could you tell us for the record why you have selected the whole wheat level as the minimum level for the addition of the nutriants?

A. You may recall I selected that as not the only one, but as an optional one. In our discussion in the office we were not cognizant of the other proposal which is a higher level than the whole wheat. We were agreed upon the fact that the whole wheat should certainly be the minimum but a higher level would be desirable, especially in the B complex, and since such a higher level has been proposed we would certainly be in favor of it.

Q. Do you deem it more in the interest of consumers and more in the promotion of honesty and fair deal-
1947 ing, that the minimum levels be based upon some scientific calculation of daily in-take than upon the accidental content of the whole wheat berry?

A. It would be hard to answer that in a general way, in this specific case I would say that anything which increases the consumption of Vitamin B without increasing the cost and is able to reach such a large number of consumers as this would be highly desirable, because of the widespread Vitamin B deficiency.

Q. And you would have no opinion as to which would be the best way of proceeding to promote honesty and fair dealing in the interest of consumers in a program of fortification of flour?

A. Of flour specifically?

Q. Yes.

A. I would rather not hazard an opinion on that, since I haven't made a careful study of the problem, and since so many people who are better qualified to do so than I have already expressed their opinions on it.

Q. I think that that is all.

Cross-Examination by Mr. Campbell.

Q. I would like to ask just one question, and that is about the name. If a separate standard of identity is established and promulgated for this flour containing
1948 the added nutrient, was it your idea that you would call it fortified flour?

A. Yes, that was the suggestion that I made.

Q. Do you think that that would convey any special information to the consumer?

A. I think that any name that was selected would not immediately convey the idea to the consumer, I think it is absolutely essential to educate them to know what the term means before it will convey such meaning to them.

Q. Were you present when Mr. Hardenbergh testified last Tuesday?

A. No, but I have read his testimony.

Q. You understand that it was his position that there was really no pride of authorship as to that term "Vimin", and that it was perfectly agreeable to the industry that any other name that was appropriate might be selected, in order to make it distinctive and one that would not be misleading to the consumer?

A. Yes.

(Whereupon, the then following discussion, by direction of the Presiding Officer, was not placed on the record.)

The Witness: I think many consumers have been informed as to the significance of the term "fortified." It has been applied to a great many things. The one
1949 that I can think of off-hand is the various fish liver oils which have been strengthened, or brought up to abnormal strength with additional vitamins, and some with additional minerals. We, too, would be perfectly open to a new suggestion on a name. The only reason I spoke for fortified was because it seems preferrable to anything that had been suggested so far.

Q. But you are perfectly open-minded for a selection of a name that might even define it better from the consumers standpoint than the word "fortified"?

A. Certainly, it is just that I haven't heard one so far.

Q. You testified about these other hearings, and advocated the use of simplified nomenclature. What is your idea, for instance take specifically B_1. Would you call that thiamin or thiamin chloride, or B_1.

A. I haven't a copy here of the proposed standard, but as I recollect the dietary foods names suggested were Vitamin B_1 and riboflavin, and no name was suggested for the palagra-preventive factor, because it was not in the list of vitamins for which permissible claims or rather for which claims are permissible, but whatever the names are that are decided upon, I think the essential thing is that one of the names should be used throughout.

I am holding no brief for either thiamin or B_1, I
1950 simply say that we shouldn't get B_1 on one label and thiamin on another.

Q. Did you hear the suggestion here the other day as to the probable effect on some of the consumers if the word "nicotinic acid" was used, as possibly conveying the impression that there was some tobacco or cigarettes in the product?

A. Yes, I heard that testimony.

Q. What is your opinion, from your relationship to this consumer organization, what have you to say about that?

A. Well, I can only give you a personal opinion on it, and my personal opinion is worth nothing as a consumer in this respect because I have never questioned them on it. I would be inclined to think that if such an impression exists it could be eradicated rather easily.

Q. That is all.

Presiding Officer Willcox: You spoke, I think, Miss Ross, of fortified as a name already in use. Do you know whether it is now in use in connection with flour?

The Witness: I have never seen it used in connection with flour.

Presiding Officer Willcox: Suppose that there were to be more than one standard established. Suppose one proposal that a flour were permitted, with any one of these ingredients might be marketed under one name
1951 which would indicate that ingredient, and another flour which would have a certain defined group of

them, would you feel that the word "fortified" was more appropriate to one of those indentities than to the other, and if so to which?

Do you get what I mean?

The Witness: Yes, I think that I see what you mean.

Presiding Officer Willcox: Perhaps I can make it more specific. There is a suggestion that one separate identity be established for flour with either B_1 or calcium, or nicotinic acid, or other products, or any combination of those that fell short of another identity which would be established, which would include the three or four elements represented by the nutritionists as a desirable thing in a generally reconstituted flour?

The Witness: To answer that, I can say "we" here, because it is part of the thing that we discussed, we feel that a flour should not be placed on the market as a fortified or whatever you want to call the flour, unless it does contain at least Vitamin B_1, nicotinic acid, iron, and possibly calcium, for the reasons that I have mentioned before, that is that they are needed ingredients, and they can be added at a low cost.

For that reason then, flour with only one of these
1952 factors should we feel not be permitted to make use of the term "fortified" or whatever term is applied to flours.

Now, whether another name should be applied to the flours which are fortified with optional plus required ingredients, is rather difficult to say. We have made no studies on what consumer reaction would normally be to such a thing, and I would be inclined to feel that a single name with a list of the ingredients would be the simplest and least confusing, and therefore to the best interests of the consumer.

Presiding Officer Willcox: Well, wouldn't you favor a name which would automatically indicate the presence of three or four ingredients you mentioned as most important, without any listing?

The Witness: Could you give me an example of that. I am not sure that I understand.

Presiding Officer Willcox: Let us assume that you used the word "fortified," or the word suggested by the industry, "Vimin," and that that word necessarily indicated the presence of B_1, nicotinic acid, and iron, at least and possibly calcium. Would you feel that that would meet

the necessity when the public came to learn that those three or four elements were indicated by that one word?

The Witness: Yes, I think that that would cer-
1953 tainly be adequate, and on a more highly fortified flour the other added ingredients should be listed.

Presiding Officer Willcox: And also on a less fortified product, which would not use that one word, but would have some other indication of what other ingredients had been added?

The Witness: Yes.

Presiding Officer Willcox: Are there any more questions?

If there are no further questions, the witness is excused.

(Whereupon, the witness is excused.) Whereupon

CHARLOTTE CHATFIELD was called as a witness for and on behalf of consumers, and having been previously sworn, was examined and testified as follows:

Direct Examination.

The Witness: I wanted to add a statement to what I gave before, and this statement is one that has been viewed and approved by several other people in the Bureau of Home Economics. The precise statement has been approved by Dr. Louise Stanley, Dr. Lela E. Booher, and Dr. Hazel K. Stiebling. It is in substantial agreement with the opinion of Dr. Helen S. Mitchell and Dr.
1954 Elsa Orant Keiles, also of the Bureau of Home Economics, although they did not see this form and officially approve it. I will read this prepared statement:

Nutritionists in the Bureau of Home Economics recognize the advantages to the public of a flour that is fortified or reinforced with certain minerals and vitamins. Required additions in the reinforcement or fortification of flours should be thiamin and iron. Optional additions may be nicotinic acid, riboflavin and Calcium. We do not recommend the inclusion of Vitamins D or C.

We oppose any regulation that will necessitate the addition of any substance, even thiamin, to all wheat flour produced. We recommend promulgation of standards for reinforced flour that will maintain a relationship between this product and the natural cereal. Therefore, we rec-

ommend using whole wheat or a long extraction flour as the appropriate criterion for setting the levels of nutrients to be added rather than attempting to make of reinforced flour a product that will approach a complete ration. The maximum nutritive value should not be greater than double the minimum suggested. The objection to setting maxima that are higher than double the minima is that a confusing variety of claims are likely to be made for products containing higher quantities.

1955 Reinforced flour should not contain enough of the optional ingredients to make the product appear to be a substitute for natural foods other than wheat that are good sources of these nutrients in usual American diets. Special dietary flours containing unusually large proportion of nicotinic acid, riboflavin and calcium, and other nutrients, should be permitted for emergency use upon recommendation of proper authorities.

That completes the prepared statement.

I think it is necessary to explain that the purpose of this last part of the statement on special dietary flours was the fear on the part of one or two of the nutritionists that if they indicated that the maximum should be not over double the minimum that it would preclude making up particular mixtures for particular purposes. They did not understand, I think, that such flours need not be standardized and that they would always be permissible without a standard. It was misunderstandings on the part of some of these people that if they had indicated that they should not, or that the maxima should not be over double the minima, that they would thereby be preventing the distribution under particular situations of flours that had a peculiar value in a given situation.

The statement does not cover any quantities per
1956 pound but it is necessary to explain here that these nutritionists in the Bureau of Home Economic understand that if they should make either long extraction flour or whole wheat flour, the criterion for setting these levels, that the quantities of calcium and of riboflavin that would be added are not particularly large quantities, that they are not sufficient to make a major change in the total diet. Nevertheless, if these substances are added as optional ingredients, they believed that the level should be set in relation to whole wheat or to a long extraction flour.

Cross-Examination by Mr. Goodrich.

Q. Miss Chatfield, you might explain for the record who Dr. Stanley and Dr. Booher and Dr. Stiebling are so that their opinions will be given proper weight.

A. Dr. Louise Stanley is the Chief of the Bureau of Home Economics; Dr. Lela E. Booher is Chief of the Food and Nutrition Division of the Bureau of Home Economics.

Q. She is a recognized authority on vitamin questions, is she not?

A. Yes; and Dr. Hazel K. Stiebling is a nutritionist whose work has been cited at some length in this hearing.

Q. The Department of Agriculture Circular 507 was prepared by Dr. Stiebling and her associates, I believe?

1957 A. Yes. Dr. Helen S. Mitchell is a recognized authority in the field of nutrition, at present employed in the Department in connection with work of the Bureau of Home Economics, and advising Mr. M. L. Wilson, who is advising Miss Elliot.

Q. Miss Elliot is the consumer representative on the National Defense Advisory Council?

A. Yes.

Q. And Mr. Wilson is advisor to her, and one of his associates is Dr. Helen S. Mitchell?

A. Yes, Dr. Elsa Orent Keiles is in the Food Composition Section of the Bureau of Home Economics, and formerly an associate of Dr. McCollum and joint author with him of a book that has previously been mentioned.

I guess that that identifies them.

By Mr. Goodrich:

Q. Has your Department decided upon, with a view of recommending for this flour, reinforced flour?

A. No, we have not proposed a name for it. The opinion seemed to be opposed to calling it restored flour, as had previously been suggested, but the stand, so far, has been wholly negative in the matter of naming. No one has proposed a name that anyone else would agree with.

Q. Can you tell us why the whole wheat level or the long extraction flour level was chosen as a proper place to fix the minimum requirements upon the several

1958 place to fix the minimum requirements upon the several nutrients to be added to flour?

A. I think so. Some of those reasons were given as my reasons, I think, in my previous testimony. The opinion seemed to be, as we indicated, that setting it in relation to the total day's requirement was less satisfactory than relating it to a food, the composition of which is already fairly well known.

The product, if it were made to contain as much calcium and as much riboflavin as were proposed by some of the others, would be out of all semblance of cereal products generally. It would lose its character as a cereal product, and would be a more sophisticated type of product than one that attempted to approach the levels in a natural product such as whole wheat, or an existing product such as long extfaction flour.

It is true that if it were made in a pattern of whole wheat that it would not have any greater value as a source of calcium, or as a source of riboflavin than whole wheat has, but there is a general recognition on the part of some consumers, as to what place whole wheat has in the diet, and it would be more easily identified by some consumers as having a certain character. If it contained these higher quantities of calcium and riboflavin it would resemble no previous food in any way, and it would
1959 require more re-education on the part of nutritionists, and advisors to consumers, and consumers themselves, than if it could be said of the new product, this is approximately equal to some other product with which you are familiar.

Q. Have the proposed levels been discussed since the nutritionists, Dr. Sebrell, Dr. Jolliffe, Dr. Wilder, Dr. Harris, and others testified at this hearing this time?

A. Yes. It is true that neither Dr. Stanley nor these others have read all of their testimony, and that they have not been present. However, it has been explained to them that the position of Dr. Wilder, which he took in the testimony, that it differed in some respects from the position taken previously at a meeting which Dr. Stanley attended, and she and Dr. Stanley in particular believes that the position taken by that committee was a wiser position to take than the one that was taken following that by Dr. Wilder.

I have discussed that with two or three of these people.

Q. You are aware of the fact that Dr. Robert Harris, who testified on the first day of this hearing, changed his position after the testimony came in, by Drs. Wilder and

others, insofar as this restoration to the whole wheat
1960 level is concerned, and that has been explained to them?

A. I personally did not know that. I must have missed it. I think, however, that that would not have influenced their judgment.

Mr. Goodrich: Thank you. That is all.

Presiding Officer Willcox: Have you any questions, Mr. Campbell?

Mr. Campbell: I have no questions.

Miss Ross: I have a question that I would like to ask.

Cross-Examination by Miss Ross.

Q. At what levels specifically do you place long extraction flour, what percentage extraction?

A. I had in mind 85 per cent extraction, and by that I mean 85 per cent of the whole grain.

Miss Ross: That is all.

Presiding Officer Willcox: In recommending against Vitamin D, you are basing that simply on your general position of restoration, and the fact that whole wheat flour does not contain any significant amount of Vitamin D, is that true, or do you have any affirmative objection to it?

The Witness: That is the primary basis. It was also mentioned in a conference on this subject, that
1961 there were other foods more appropriate to carry Vitamin D.

Miss Ross: I have another question, if I may.

By Miss Ross:

Q. Why do you place nicotinic acid in the optional rather than the required list of ingredients?

A. I think that there were two reasons, and both of them relate to insufficient knowledge on the subject. One is that we are not prepared to state what is the usual or average level of nicotinic acid in whole wheat, and the other that there may be some technical difficulties in accomplishing a standard that could be used by everyone.

Mr. Goodrich: You mean the standard used by the enforcing officials or one to be used by the manufacturer, the difficulties of assay, which have dictated your opinion on nicotinic acid?

The Witness: I believe that that was the primary reason. They also felt that there was some uncertainty as to the level usual in whole wheat.

Cross-Examination by Mr. Thode.

Q. Miss Chatfield, in recommending the whole wheat level, you were not suggesting that a definition should be based on anything so indefinite as a mere reference to whole wheat level; you were going to suggest a con-1962 version of that into units, were you not?

A. I was not prepared to state the levels that we consider have been established as the average composition of whole wheat, or of 85 per cent extraction flour. There has been some cumulation of testimony on the composition of whole wheat and a certain amount of it on the composition of such a flour, but I was not prepared to offer those figures.

Q. It would be your idea that they should be determined and that then their unit would be standard, rather than any further reference to whole wheat in the definition?

A. Yes.

Mr. Thode: Thank you.

Presiding Officer Willcox: Are there are further questions? (No response.)

(Witness excused.)

GOVERNMENT EXHIBIT No. 3

FARINA

TABLE XVII

Sample No.	Date collected	Moisture	Ash	Protein	Particle Size: Remained on 20 mesh sieve	Particle Size: Passed through 100 mesh sieve
			IDAHO			
90028-D	1/16/40	13 46	0 61	9 07	0 40	2 10
			ILLINOIS			
46747-D	1/8/40	10 23	0 31	10 41	0 00	0 10
61785-D	1/4/40	12 70	0 37	10 72	0 02	1 18 (a)
61788-D	1/5/40	11 02	0 37	11 61	0 10	0 09
70156-D	1/8/40	11 47	0 33	10 60	0 00	0 26
74431-D	12/28/39	9 35	0 34	12 20	0 11	0 15
74432-D	12/28/39	9 73	0 33	10 32	0 07	0 35
75279-D	1/4/40	11 39	0 37	10 86	0 00	0 40
83543-D	1/19/40	11 47	0 35	11 34	0 00	0 40
84584-D	1/12/40	11 67	0 78	12 03	0 10	1 00 (b)
84585-D	1/12/40	12 18	0 35	10 37	0 10	1 30
97323-D	1/16/40	9 92	0 69	11 42	0 00	2 00 (c)
97407-D	1/19/40	10 35	0 51	11 42	0 00	Trace
			INDIANA			
46575-D	5/15/39	13 11	0 75	12 10	4 13	0 54 (d)
			IOWA			
46746-D	1/8/40	9 56	0 39	11 14	0 00	1 70 (e)
75274-D	1/2/40	13 43	0 37	10 25	0 00	0 40
82387-D	1/12/40	11 26	0 38	10 72	0 00	3 60 (f)
			KANSAS			
46748-D	1/8/40	10 13	0 40	10 70	0 00	0 40
46749-D	1/9/40	10 24	0 39	11 41	0 00	0 10
80015-D	1/20/40	13 63	0 38	11 21	0 00	0 30
			MICHIGAN			
46584-D	5/25/39	13 98	0 49	12 27	0 66	0 20

(a) 1/5 of 1% Irradiated Dry Yeast
(b) Labeled Durum Farina
(c) 1½% Irradiated Dry Yeast added
(d) Breakfast Food—Unpurified Middlings, Hard Wheat.
(e) ½% Dry Yeast Added
(f) 1/5% of 1% Dry Yeast added

FARINA

TABLE XVII

Sample No.	Date collected	Moisture	Ash	Protein	Particle Size: Remained on 20 mesh sieve	Particle Size: Passed through 100 mesh sieve	
			MINNESOTA				
48709-D	6/27/39	14 54	0 35	10 00	0 03	0 20	
48717-D	6/31/39	14 52	0 38	11 74	0 03	0 11	
48721-D	7/12/39	14 52	0 37	9 73	0 04	0 16	
61290-D	1/10/40	11 67	0 42	11 64	0 29	0 72	
73972-D	1/4/40	11 09	0 34	10 83	0 02	0 28	
73977-D	1/11/40	13 85	0 34	9 80	0 00	0 60	
74429-D	12/28/39	12 08	0 44	11 29	0 02	0 38	
74430-D	12/28/39	14 29	0 37	11 91	0 06	0 47	
80016-D	1/20/40	12 63	0 36	10 99	0 00	0 20	
80088-D	1/12/40	14 27	0 44	12 69	0 00	1 09	
80091-D	1/12/40	12 66	0 36	11 80	0 00	2 21	
			MISSOURI				
61289-D	1/10/40	10 92	3 07	13 28	0 05	3 48	(g)
66520-D	1/3/40	14 32	0 36	10 77	0 01	0 15	
66521-D	1/3/40	15 28	0 34	10 73	0 00	0 37	
66527-D	1/10/40	14 07	0 34	10 69	0 00	0 04	
66528-D	1/11/40	14 69	0 33	11 10	0 00	0 25	
66530-D	1/11/40	14 80	0 36	10 79	0 02	0 23	
66639-D	8/23/39	14 54	0 35	12 14	0 00	0 43	
77732-D	1/16/40	13 48	0 36	10 91	0 02	0 24	
80017-D	1/20/40	13 44	0 36	11 48	0 00	0 40	
82388-D	1/12/40	10 33	0 37	11 34	0 10	0 90	
84582-D	1/12/40	10 65	0 48	11 84	0 00	1 00	(h)
59072-D	1/3/40	12 24	0 36	11 93	0 00	0 66	
80089-D	1/12/40	12 80	0 34	12 13	0 00	0 93	
80090-D	1/12/40	14 37	0 35	11 45	0 00	0 76	
97405-D	1/19/40	8 87	3 44	14 61	0 00	3 00	(i)
			NEBRASKA				
70157-D	1/8/40	12 64	0 37	12 43	0 00	0 23	
97406-D	1/19/40	11 06	0 38	11 28	0 00	0 50	
			NEW YORK				
73973-D	1/4/40	10 78	0 38	10 92	0 07	0 10	
81141-D	12/29/39	11 32	0 39	10 86	0 00	0 01	
81142-D	12/29/39	14 71	0 31	12 46	0 00	0 80	(Fine)
		14 66	0 39	11 28	0 03	0 10	(Coarse)

(g) Labeled "Super Farina Richer than whole wheat in Vitamin B & Minerals"
(h) Labeled—Breakfast Food
(i) Labeled "Super Farina Richer than whole wheat in Vitamin B & Minerals"

FARINA

TABLE XVII

Sample No.	Date collected	Moisture	Ash	Protein	Particle Size: Remained on 20 mesh sieve	Particle Size: Passed through 100 mesh sieve
OREGON						
57371-D	1/12/40	14 08	0 45	8 72	0 00	0 70
57372-D	1/12/40	12 19	0 43	7 59	0 20	0 40
83499-D	1/19/40	11 17	0 54	7 73	0 25	0 40
83548-D	1/23/40	14 12	0 33	6 60	0 00	0 60
PENNSYLVANIA						
70184-D	1/23/40	12 77	0 37	11 22	0 00	0 17
TEXAS						
38336-D (8)	6/16/39	12 84	0 37	11 93	0 00	0 10
38357-D (7)	6/17/39	12 71	0 39	11 53	0 01	0 08 (j)
62716-D	6/2/39	14 36	0 39	12 11	0 01	0 46
62722-D	6/8/39	14 26	0 45	10 70	0 01	0 14
WASHINGTON						
51038-D	6/20/39	11 73	0 39	12 05	0 00	0 70
57369-D	1/12/40	13 66	0 36	9 28	0 10	1 00
57370-D	1/12/40	11 99	0 35	9 41	0 05	0 30
64076-D	6/23/39	13 18	0 64	11 98	2 00	1 10
64097-D	6/29/39	12 52	0 63	8 95	0 00	1 45
67987-D	9/11/39	13 56	0 36	11 19	0 00	1 21
90709-D	1/18/40	13 43	0 51	7 05	0 20	1 55

(j) Wheat Cereal

GENERAL MILLS EXHIBIT NO. "E."

Restored Wheat Flour.

15.010

(a) Restored wheat flour is the milled wheat product prepared to provide the essential nutritive elements of the whole grain and contains the factors vitamins B1, B2, Iron, and Calcium in amounts not less than the minima hereinafter specified. It is prepared by grinding and bolting cleaned wheat, except durum; such proportion of malted wheat and/or flour may be used as compensates for any natural deficiency of enzymes. The final bolting is through a cloth having openings not larger than those of No. 100 woven wire cloth which complies with the specifications for such cloth in "Standard Specifications for Sieves" published March 1, 1940 by the U. S. Department of Commerce, National Bureau of Standards. It is so freed from bran coats or germ, or both, that the percent of ash contained therein is not more than the sum of one-twentieth of the percent of protein contained therein and 0.5. Its moisture content is not more than 15%. Unless such addition conceals damage or inferiority of the flour or makes it appear better or of greater value than it is, one or any combination of two or more of the following optional bleaching ingredients may be added in a quantity not more than sufficient for bleaching, or in case such ingredient has an artificial aging effect, in a quantity not more than sufficient for bleaching and such artificial aging effect:

(1) Oxides of nitrogen.
(2) Chlorine.
(3) Nitrosyl chloride.
(4) Nitrogen trichloride.
(5) Benzoyl peroxide.

(b) When any optional bleaching ingredient is used, the label shall bear the word "Bleached". Wherever the name "Restored Wheat Flour" appears on the label so conspicuously as to be easily seen under customary conditions of purchase, such word shall immediately and conspicuously precede or follow such name, without intervening written, printed, or graphic matter, unless the word "Flour" is part of a previously registered or established trade-mark, in which case the name flour, white flour, wheat

flour or plain flour shall again appear on the label so conspicuously as to be easily seen under customary conditions of purchase, with the word "Bleached" immediately preceding or following such name without intervening written, printed, or graphic matter.

(c) For the purpose of this section—

(1) Ash content is determined by the method prescribed in the book "Official and Tentative Methods of Analysis of the Association of Official Agricultural Chemists", Fourth Edition, 1935, page 207, under "Method 1—Official".

(2) Protein content is 5.7 times nitrogen content as determined by the method prescribed in such book on page 25, under "Kjeldahl-Gunning-Arnold Method—Official".

(3) Moisture content is determined by the method prescribed in such book on page 206, under "Vacuum Oven Method—Official".

(d) It shall contain not less than:

1. 1.4 International units of Vitamin B1 (Thiamin) per gram (40 units per ounce).
2. 2.0 micrograms of riboflavin per gram (56 micrograms per ounce).
3. 0.04% calcium (as Ca)
4. 0.004% iron (as Fe)

It may also contain one or more of the following optional ingredients:

1. Nicotinic acid and/or nicotinic acid amide
2. Pantothenic acid
3. Vitamin B6
4. Vitamin E
5. Compounds of phosphorous

The required and optional nutritive ingredients may be supplied in an amount not exceeding ____% of the weight of the finished product by the addition of edible mineral compounds and by the addition of vitamins in purified form and/or in concentrates, obtained either from natural sources or by synthesis. When any vitamin or mineral added in conformity with this section (15.010) is in the form of a concentrate it may be accompanied by any other vitamins and minerals naturally present in the concentrate.

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OTHER PEOPLES' EXHIBIT O.

THE RETENTION OF CALCIUM AND PHOSPHORUS BY PRE-SCHOOL CHILDREN[1]

H. B. PIERCE, R. G. DAGGS,[2] M. B. MESERVEY[2] AND W. J. SIMCOX
WITH THE TECHNICAL ASSISTANCE OF D. H. HOWE AND M. W. FOOTE
Departments of Biochemistry and Physiology, College of Medicine, University of Vermont, Burlington

ONE FIGURE

(Received for publication December 15, 1939)

The feasibility of supplementing the diets of children with certain vitamins and minerals has been demonstrated by Aykroyd and Krishnan ('38), Privitera ('38), Schlutz and his associates ('38), Summerfeldt and Ross ('38), and Tisdall et al. ('30). From past experience it is known that the utilization of minerals is influenced by the source. Thus, the question arises as to the availability of added substances in fortified foods for use by the human body.

Several studies of the calcium metabolism of children have been made in recent years (Daniels et al., '34, '35; Outhouse et al., '39; Kinsman and associates, '39). A survey of the available data shows that marked variations in calcium retention have been noted. Furthermore, individual retentions differ materially from time to time in the same child. Fairbanks and Mitchell ('36) have shown with growing rats that calcium requirements can be determined only when the body stores have been saturated by appropriate pre-feeding.

Several investigations comparing the availability of calcium and phosphorus from milk and from inorganic sources have

[1] This investigation was aided by a grant from the Cream of Wheat Corporation, Minneapolis, Minn.

[2] The data on phosphorus metabolism were presented by Mr. Meservey in partial fulfillment of the requirements for the degree of master of science, University of Vermont, June, 1939.

been made: A study of these data, along with their own, led Henry and Kon ('39) to make the following statement, "As far as they go, these studies appear to indicate that if there is a difference between the availabilities of calcium from milk and from inorganic sources it cannot be very marked and our metabolic experiments confirm such a view."

The object of this study has been to determine whether the calcium of an alkaline salt mixture added to a wheat farina would be as well utilized by pre-school children as an equivalent amount of this element supplied by milk. After adequate pre-feeding to insure saturation with calcium and phosphorus, part of the milk of the basal diet was omitted, and the calcium in this quantity of milk was replaced by an equivalent amount furnished by the salt mixture[3] in the fortified cereal.

EXPERIMENTAL

Ten children, six boys and four girls, whose ages, weights, and heights at the beginning and end of the experiment are shown in table 1, were selected to serve as subjects. A routine was established to make a program as nearly normal as possible within the rigid control required. In inclement weather, the children received exposure to rays from an ultraviolet lamp for 15 minutes daily.

The diets were similar to those used by Daniels et al. ('34). A typical diet for one subject throughout the study is illustrated in table 2. The basal diet was planned so that approximately 50 mg. of calcium per kilogram body weight per day or 80% of the total ingested was supplied by milk and the remainder by the solid food. During experimental periods, 200 mg. of milk calcium were replaced by 200 mg. of calcium in the fortified cereal. The food was supplemented with 1800 U.S.P. units of vitamin D, 12,000 U.S.P. units of vitamin A, and 300 U.S.P. units of thiamin hydrochloride daily. Distilled water was used for drinking and cooking.

The children were divided into two groups as evenly matched as possible with regard to weight and age. These two groups

[3] A mixture of calcium, sodium and iron phosphates.

TABLE 1

Growth record of children

Subject	Group	Sex	BEGINNING Age	Weight	Height	END Age	Weight	Height	Gain in weight	Gain in height	Expected gain [1] Weight	Expected gain [1] Height
			yrs. mos	*kg.*	*cm.*	*yrs. mos*	*kg.*	*cm.*	*kg.*	*cm.*	*kg.*	*cm.*
1	LP	F	5 – 10	16.3	102.2	6 – 4	18.5	105.4	2.2	3.2		
2	LP	F	4 – 2	16.2	101.0	4 – 8	18.4	105.4	2.0	4.4	1.1	4.1
3	PL	M	5 – 0	18.5	102.9	5 – 6	20.3	108.6	1.8	5.7	1.1	3.4
4	PL	M	5 – 4	18.0	106.7	5 – 10	20.4	111.1	2.4	4.4	0.7	3.5
5	PL	F	2 – 11	14.5	95.3	3 – 5	17.0	98.4	2.5	3.1	0.2	2.5
6	LP	M	3 – 7	17.6	109.5	4 – 1	19.6	113.7	2.0	4.2	1.0	3.6
7	LP	M	5 – 5	17.7	99.7	5 – 11	19.1	104.8	1.4	5.1	0.5	2.6
8	LP	M	5 – 4	20.1	114.3	5 – 10	22.9	120.0	2.8	5.7	0.7	2.6
9	PL	F	4 – 2	15.5	99.1	4 – 8	17.3	103.5	1.8	4.4	1.1	4.1
10	PL	M	4 – 0	14.9	94.6	4 – 6	17.0	97.8	2.1	3.2	0.9	3.5

[1] Based on data at Iowa Child Research Station ('29).

TABLE 2

Sample diets. Child no. 22 in group 1. Figures are in grams or cubic centimeters unless noted differently

	PERIOD 1	PERIOD 2	PERIOD 3	PERIOD 4	PERIOD 5
Breakfast					
Oatmeal	10	10	10	10	—
Cream of Wheat	—	—	—	—	15 New
Sugar	7	7	9	7	7
Milk	225	225	162	225	225
Bread	15	15	15	15	15
Butter	5	5	5	5	8
Jelly	10	10	10	10	10
Prunes	40	40	40	40	40
Egg	50	50	50	50	50
Mid A.M.					
Orange juice	120	120	120	120	120
Vit. B tablets	1 tablet	1 tablet	1 tablet	1 tablet	1 tablet
Oleum Perco. (vit. D)	10 drops	10 drops	10 drops	10 drops	10 drops
Dinner					
Cream of Wheat	—	—	—	—	10 New
Beef	30	30	30	30	30
Potato	85	85	85	85	85
Beans	40	—	—	40	—
Carrots	—	40	40	—	40
Bread	15	15	15	15	15
Butter	10	10	10	10	10
Milk	20	20	20	20	20
Tomato juice	110	110	110	110	110
Doughnut	—	—	23	—	—
Mid P.M.					
Banana	70	70	70	70	70
Milk	218	218	—	218	50
Brazil nuts	—	—	14	—	—
Supper					
Cream of Wheat	15 Old	15 Old	15 Old	15 Old	15 New
Sugar	7	7	9	7	7
Milk	225	225	162	225	225
Bread	15	15	15	15	15
Butter	5	5	5	5	9
Jelly	10	10	10	10	10
Apple sauce	60	60	60	60	60
Chocolate	15	15	15	15	15
Ca lactate	2.856*	—	—	—	—
Triple $^{P}O_{4}$	—	—	—	1.213*	—

* Equivalent to 256 mg. calcium.

are designated as LP and PL, respectively; the former being saturated with calcium from lactate in the first and calcium from phosphate in the second saturation period. PL children were saturated with calcium from phosphate in the first and calcium from lactate in the second saturation period. The experiment was divided into five metabolism periods as shown in table 3.

TABLE 3

Diet periods

GROUP	PERIOD 1 6 WEEKS	PERIOD 2 5 WEEKS	PERIOD 3 2 WEEKS	PERIOD 4 4 WEEKS	PERIOD 5 6 WEEKS
LP	Basal diet plus 200–256 mg. Ca from lactate	Basal diet	Ca intake reduced to approximately ⅔ that of basal diet	Basal diet plus 256 mg. Ca from triple phosphate	Basal diet except 200 mg. milk Ca replaced by 200 mg. Ca supplied by fortified farina
PL	Basal diet plus 200–256 mg. Ca from triple phosphate	Basal diet except 200 mg. milk Ca replaced by 200 mg. Ca supplied by fortified farina	Ca intake reduced to approximately ⅔ that of basal diet	Basal diet plus 256 mg. Ca from lactate	Basal diet

To rule out variations which might be assigned to changes of weather, season and age, the periods for the PL group were reversed and the sequence was 4, 5, 3, 1, 2.

The dietary routine was interrupted for a few days between periods, care being taken that the calcium intake remained the same as that of the preceding period.

DISCUSSION OF RESULTS

Calcium. By referring to table 4 and figure 1, it may be seen that retention during the first two periods was higher than that noted during the last three. It has been noted in other studies of this nature that previous depletion due to inadequate mineral intake or poor utilization may be responsible for early high retentions. In period 1 children (LP), being saturated with the lactate, retained more calcium than those obtaining this element from the phosphate mixture. Using the data for

TABLE 4

Calcium and phosphorus metabolism

PERIOD	GROUP	CALCIUM							PHOSPHORUS						Ca : P	Ca : P FOOD	WEEKLY STOOL WEIGHT	NITROGEN RETENTION PER KG. PER DAY
		Weekly intake	Weekly output			Weekly retention		Ca per gram stool	Weekly intake	Weekly output			Weekly retention					
			Amount	Feces	Urine					Amount	Feces	Urine						
		gm.	gm.	%	%	gm.	%	mg.	gm.	gm.	%	%	gm.	%			gm.	mg.
1	LP[2]	9.19	7.08	95.9	4.1	2.11	22.9	10.1	8.72	7.37	42.7	57.3	1.35	15.5	1.58	1.05	682	
1	PL[3]	9.17	7.57	95.2	4.8	1.60	17.4	11.1	9.80	8.52	38.2	61.8	1.28	13.2	1.21	0.94	657	
2	LP	8.14	6.43	93.3	6.7	1.71	21.1	10.1	8.46	7.63	44.6	55.4	0.83	10.4	2.04	0.96	580	61.2
2	PL	7.90	5.99	91.5	8.5	1.91	24.1	9.7	8.43	7.33	35.5	64.5	1.10	13.1	1.75	0.94	571	53.6
3	LP	5.01	4.66	90.0	10.0	0.95	18.9	6.8	7.33	6.68	43.4	56.6	0.65	8.8	1.66	0.68	542	
3	PL	4.73	3.90	88.2	11.8	0.83	17.7	6.4	7.06	6.50	39.7	60.3	0.56	8.1	1.48	0.67	547	
4	LP[3]	9.89	8.24	95.0	5.0	1.45	15.0	12.2	9.94	9.29	48.1	51.9	0.65	6.8	2.18	0.97	640	55.0
4	PL[3]	9.32	7.91	92.7	7.3	1.41	15.1	10.6	8.16	7.49	38.2	61.8	0.67	8.6	2.06	1.14	692	65.9
5	LP	8.12	6.62	93.3	6.7	1.50	18.5	11.0	8.80	7.78	43.0	57.0	1.02	11.5	1.49	0.92	563	51.9
5	PL	7.74	6.29	91.8	8.2	1.45	18.7	10.3	8.41	7.54	36.5	63.5	0.89	10.4	1.65	0.92	566	53.1
Av.	LP[4]	8.03	6.42	93.5	6.5	1.54	19.3	10.9[4]	8.64	7.75	44.4	55.6	0.90	10.6	1.79	0.92	616	56.0
Av.	PL	7.77	6.33	91.9	8.1	1.44	18.6	10.4[4]	8.37	7.48	37.6	62.4	0.90	10.7	1.63	0.92	621	57.2

[1] Calculated on basis of milligrams retained per kilogram body weight per day.

[2] Calcium lactate used for saturation.

[3] Tri-calcium phosphate used for saturation.

[4] Data of period 3 omitted in computing average.

Wet ashing urine, feces and foods: Gerritz ('35).

Calcium: Shohl and Pedley's ('22) modification of McCrudden's ('09–'10; '11–'12) method.

Phosphorus: Mackay and Butler's modification of Mathison's method, Peters and Van Slyke ('32).

Total nitrogen: Kjeldahl method.

period 2 as a base, an equivalent of all of the calcium added and more was excreted in period 1 by both groups. Since amounts of calcium equivalent or more than equivalent to those added were excreted in the period of saturation, as compared with those where basal diets alone were used, it may be assumed that the basal diets contained adequate calcium for the needs of these children. In period 2, when the calcium intake was reduced and a comparison made of the availability of calcium derived from milk and from the fortified cereal, the latter source proved to be the better one from the standpoint of retention.

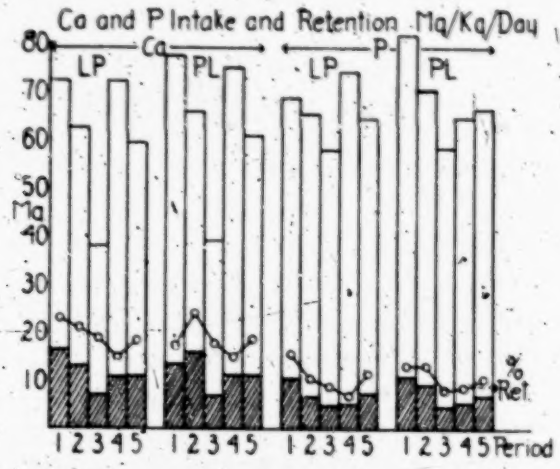

Figure 1

In period 3 the calcium-phosphorus ratio of the food, instead of being approximately 1 as in other parts of the study, approached a value of 0.7. This in itself may offer an explanation of the lowered retention. The percentage of calcium excreted in the stools, however, reached its lowest point suggesting that the disproportionate amount of phosphorus in the diet had not caused any unusual precipitation of calcium in the intestine. An adequate intake of vitamin D, however, tends to eliminate unfavorable effects due to low calcium-phosphorus ratios, and our diets contained plenty of this vitamin. Further, Sherman and Hawley ('22), using diets with low calcium-phosphorus

ratios over short periods of time, obtained data which indicated no disturbance of calcium retention.

It is interesting to note that the calcium intakes and retentions in period 3 of this study are in close agreement with those of Outhouse and her associates ('39). In the last two periods with higher intakes, the amounts retained are similar to those found by Sherman and Hawley ('22), while in the first two periods the retentions are higher. The maximum retentions did not approach those reported by Stearns and Jeans ('34). To obtain maximum retentions under the conditions of this experiment, the amount of calcium in the diet had to be greater than that suggested by Outhouse and associates ('39), but these investigators have pointed out that their data may not apply to all pre-school children. In regions of the country where there is little sunshine and where the outdoor activities of children are limited by the severity and length of the winter, it may be necessary to furnish more calcium than in regions having a more moderate climate. From our results one would conclude that the old standard of 1 gm. of calcium per day would more nearly fulfil the needs of the pre-school child than smaller amounts.

The retentions were higher in the fourth than in the preceding period and there was no significant difference between the results obtained with the two salts. Less calcium was retained by each group than in the first period. Increasing the amount of calcium resulted in a better retention of this element, but not of phosphorus (Tisdall and Drake, '38). In period 5 retentions were the same regardless of the source, showing that calcium of the fortified cereal was just as satisfactory in fulfilling the needs of the pre-school child as an equivalent amount from milk. This satisfactory utilization of calcium from an added salt is in agreement with that found by Stearns and Jeans ('34). Since the salt mixture used for fortification contained disodium phosphate, it is of interest to note that Henry and Kon ('39) found that the addition of this salt to a milk diet increased the absolute retention of calcium,

and phosphorus by rats. The calcium-phosphorus ratios of food ingested approximated 1:1 as in our diets.

If the calcium output during period 5 is compared with that of period 4, it is seen that the differences between the total excretions correspond almost exactly with the extra amounts added for saturation. This affords further confirmation of our previous assumption that the basal diets were adequate in their calcium content. Since the retentions by both groups of children were essentially the same in periods 4 and 5, it is evident the children were saturated with this element.

Statistical treatment of the data for calcium retention reveals no significant differences between the two groups except in period 2. During this time, children receiving the diet in which part of the milk calcium had been replaced by calcium from the fortified cereal retained more calcium than members of the other group. Although the retentions in period 1 appeared to favor lactate as a better source of calcium than phosphate, the observed difference proved to be insignificant.

Phosphorus. The amounts stored by the children were larger at the beginning than toward the end of this investigation. This raises the question, as with calcium, as to the effect of previous depletion upon the extent of storage. The presence of more phosphorus in the diet of the PL than in that of the LP children did not increase the retention of the former group. This observation confirms that of Wang and her associates ('29) who found that increasing the amount of phosphorus in the diet over and above requirements merely caused a larger excretion in urine and feces. During the first period, when PL children were being saturated by use of the phosphate, about 12% of the phosphorus of the added salt was retained. Quite a different result was obtained with the other children (LP) while they were being saturated with the phosphate in period 4, for none of the added phosphate phosphorus was retained; in fact an equivalent of all of the added phosphorus and more was excreted during this period. Accordingly, it may be assumed that the basal diets contained sufficient phosphorus to meet the requirements of these children. The amounts re-

tained in period 1 were alike for each group, showing that the quantity added had no effect upon retention. The data for period 2 show a better retention of phosphorus when part of the milk was replaced by fortified cereal. Admittedly, the intake per kilogram body weight per day was higher for PL children who retained the larger amount of phosphorus. Yet, with a more marked difference in the daily intake per unit of body weight in the first period, no such difference in retention was found.

The girls in each group had a lower percentage output of phosphorus in the urine than did the boys. The question may be raised as to whether this finding might be due to the urinary contamination of the feces by the girls. Extreme care was used in an effort to avoid this, and the girls always were required to empty the bladder before going to stool. The nurse in charge then watched the pails to see that no urine had been passed.

Stearns ('31) has discussed the significance of the retention ratios of calcium and phosphorus in children. A survey of the literature dealing with the calcium and phosphorus metabolism of children reveals that the retention ratios vary within wide limits over a period of time even with the same child. Our data confirm this observation, but ratios obtained by us are much higher than those listed by Stearns ('31). Our average retention ratios during 6 months were 1.79 for LP and 1.63 for PL children. These values lie within the range, namely, between 1.5 : 1 and 2 : 1, recommended by Stearns.

The calcium-phosphorus ratios of bones of children as determined by several workers show some degree of variation, the values ranging from 1.9 to 2.26. In computing the amount of phosphorus required for converting retained calcium into bone, the selection of the proper ratio is important if a correct estimate is to be made of the amount of phosphorus remaining for synthesis of soft tissues. If we accept the higher ratio of 2.26 as correct, then with any ratio lower than this, phosphorus would be available for building soft tissue. We could conclude then that at all times during this study each group was building bone and soft tissue. Our data tend to confirm the idea that

in given periods some tissues grow at a more rapid rate than others, thus requiring different amounts of phosphorus. It is interesting to point out that during period 4 when high retention ratios were found, the weekly increase in body weight of children of both groups was smaller than in any other period.

The average daily retentions of phosphorus in milligrams per kilogram body weight for the 6 months were 6.9 for the LP and 7.4 for PL children. Both of these values are slightly lower than the average daily value of 8 mg. per kilogram body weight obtained by Sherman and Hawley ('22). The average retentions found by Daniels et al. ('35) also are somewhat higher than those obtained in this study.

As with calcium, statistical treatment of the data showed no significant differences between the amounts of phosphorus stored by the two groups except in period 2. Here children (PL) on the diet in which part of the milk calcium had been replaced by calcium from the fortified cereal retained significantly more phosphorus than the other children.

Nitrogen balances were determined for 1 week in periods 2, 4, and 5, and all children were in positive balance (table 4). The highest and lowest retentions found during period 2 amounted to 93 and 41 mg. per kilogram body weight per day respectively; in period 4, to 92 and 22 mg.; and in period 5, to 64 and 37 mg. The few values obtained revealed that no one child consistently retained a large or a small amount of nitrogen. In general the retentions were somewhat lower than those found by Daniels et al. ('35).

By referring to data in table 4 it is seen that there is no evidence of any laxative effect of the salt mixture used for fortification. The average weekly weights of stools of the two groups are in close agreement throughout the study with the possible exception of period 4, in which a higher value was noted with children who were receiving calcium lactate.

To gain information as to the possible effects of the triple phosphate mixture upon acid-base balance, titratable acidity (Folin, '05) of the urine was determined during period 5. Here again there was no significant difference for the two groups,

the average daily titration expressed in cubic centimeters of N/10 alkali being 136 for the LP and 168 for the PL group. These values are in agreement with those of Hawks et al. ('37).

SUMMARY AND CONCLUSIONS

A comparison has been made between milk and a fortified cereal as sources of calcium and phosphorus for pre-school children. The subjects were four girls and six boys ranging in age from 3 to 6 years. To rule out possible variations which might be due to changes in age, weather and season, the children were divided into two groups each consisting of two girls and three boys and the sequence of diet periods was reversed.

An adequate basal diet was used. To eliminate effects of previous calcium depletion, if any, extra calcium for saturation was fed in the form of lactate or the phosphate mixture used for fortification of the cereal. Final analysis shows that there is no significant difference between the retentions of calcium and phosphorus regardless of the salt used.

With the same basal diet the retention of calcium and phosphorus was determined when 200 mg. of milk calcium was replaced by 200 mg. of calcium in the fortified cereal. In one period the storage of calcium and phosphorus was significantly better when these two elements were supplied in part by the fortified cereal rather than by milk, while in a second period of comparison the availability of calcium and phosphorus as measured by retention was the same.

The children were in positive calcium, phosphorus and nitrogen balance throughout the study and more phosphorus was stored than was required to convert retained calcium into bone.

The averages of the results obtained for two groups of children over a period of 6 months were in close agreement. The daily storage of calcium was between 11 and 12 mg. and of phosphorus between 7 and 8 mg. per kilogram body weight. About 19% of the calcium and 11% of the phosphorus were retained. All children grew at rates better than those given as normal by the Iowa Child Research Station.

For maximal retention of calcium it was necessary to have a daily intake of over 700 mg. of calcium. When a part of the milk calcium of an adequate diet was replaced by an equivalent amount supplied by tri-calcium phosphate in a fortified cereal, utilization as measured by retention was equally good from milk and cereal.

The authors wish to thank members of the Board of Managers of the Home for Destitute Children and the Supervisor, Mrs. E. L. Bessey, for their interest and cooperation in this problem. We also express our gratitude to Mrs. B. M. Wheeler and Miss Roberta Thompson for their care and supervision of the children and to Dr. C. K. Johnson for his examinations and medical care of the children.

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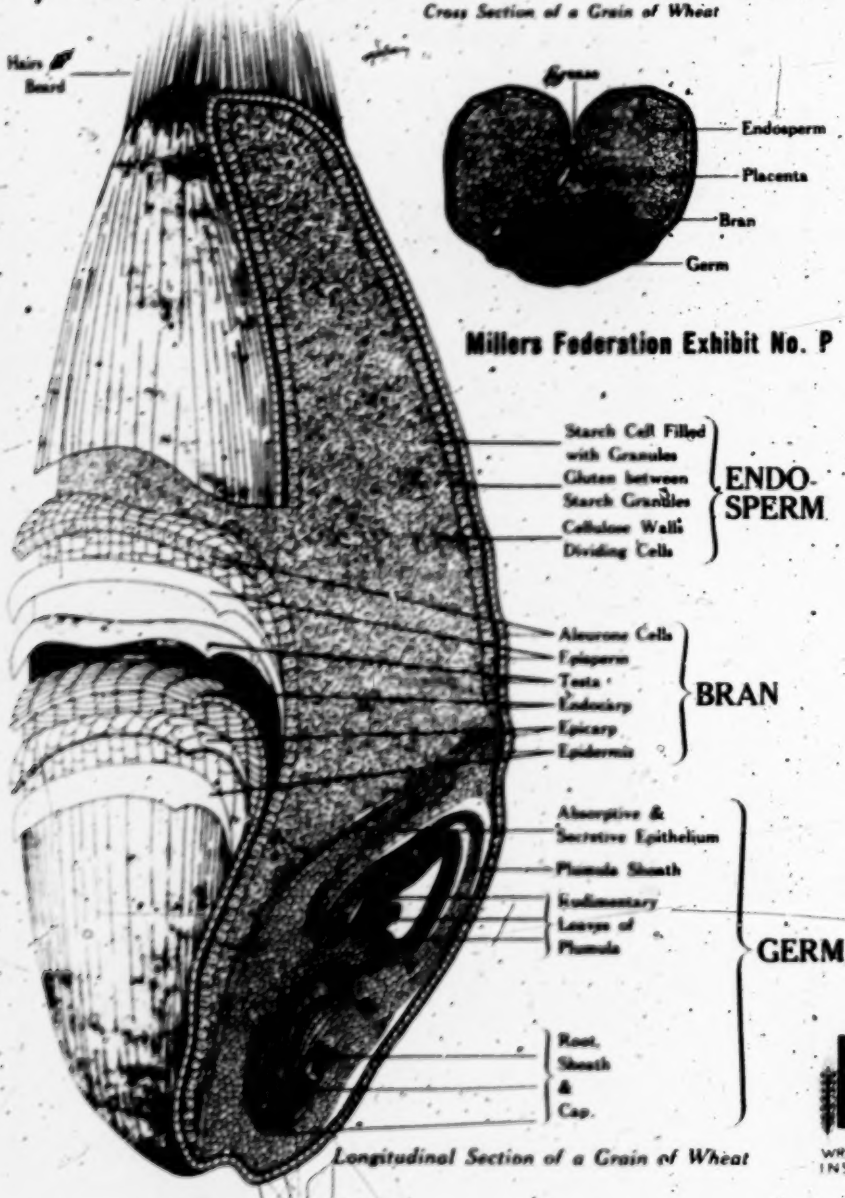
A KERNEL OF WHEAT

Cross Section of a Grain of Wheat



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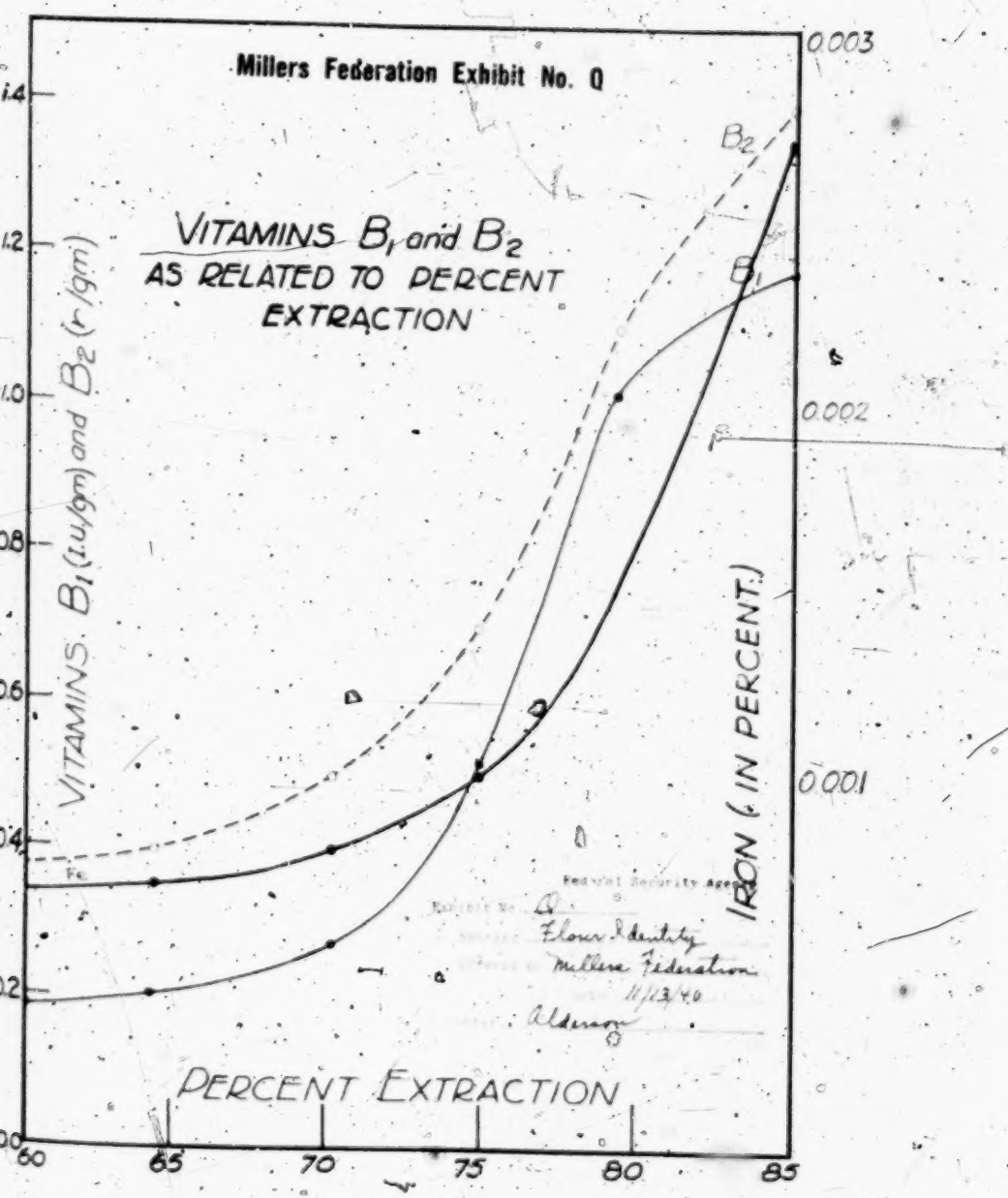
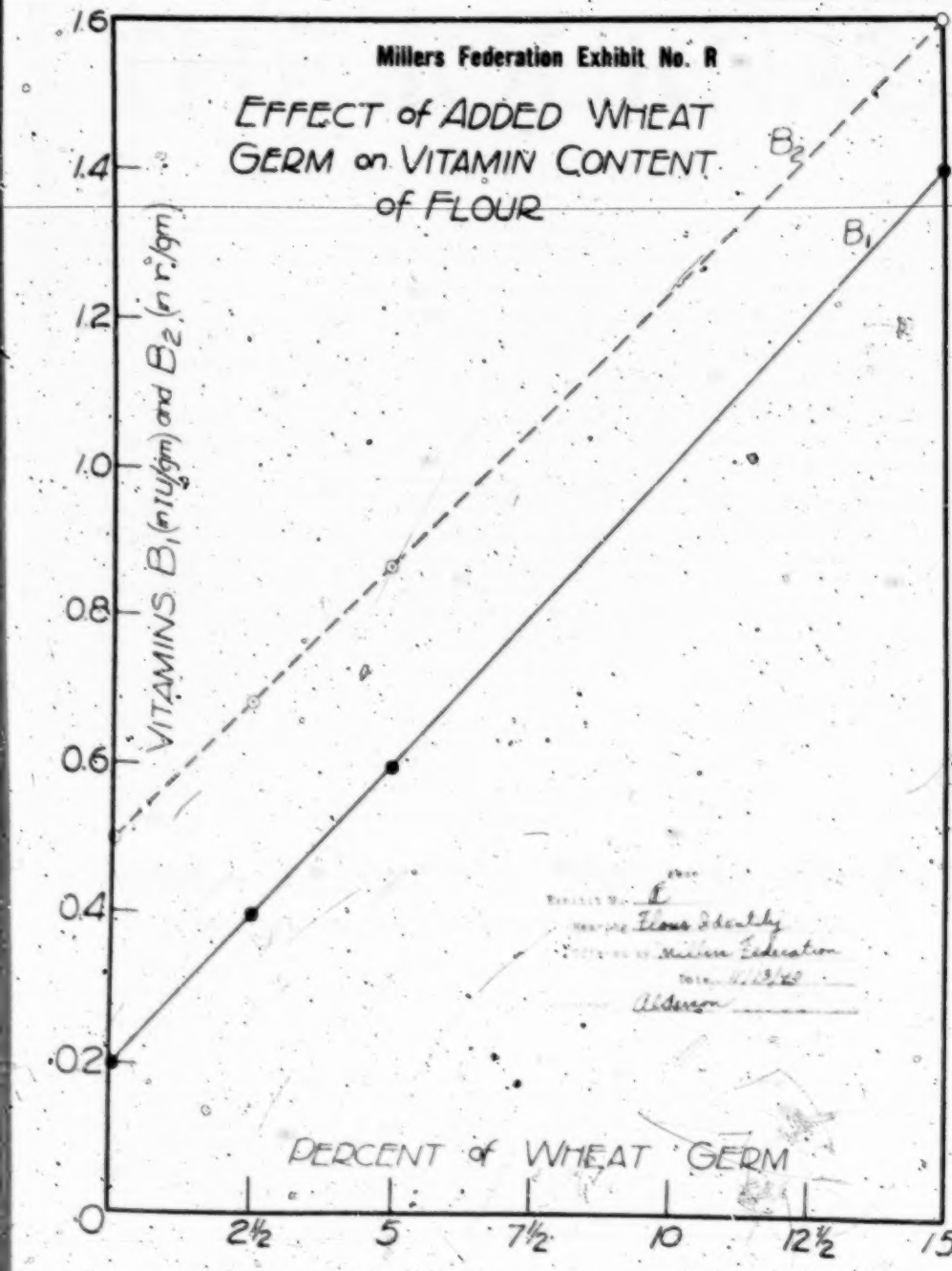
Longitudinal Section of a Grain of Wheat

WHEAT FLOUR INSTITUTE


Millers Federation Exhibit No. Q
VITAMINS B_1 and B_2
AS RELATED TO PERCENT
EXTRACTION
VITAMINS B_1 (I.U./gm) and B_2 (r/gm)
IRON (% IN PERCENT)
B_2
B_1
0.003
0.002
0.001
1.4
1.2
1.0
.08
.06
.04
.02
.00
60
65
70
75
80
85
PERCENT EXTRACTION
Flour Identity
Millers Federation
11/13/40
Aldenon


Millers Federation Exhibit No. R
EFFECT of ADDED WHEAT GERM on VITAMIN CONTENT of FLOUR
VITAMINS B_1 (in I.U./gm) and B_2 (in r./gm)
B_2
B_1
1.6
1.4
1.2
1.0
0.8
0.6
0.4
.02
0
2½
5
7½
10
12½
15
PERCENT of WHEAT GERM

Wis. Foundation Exhibit No. S

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Entered as Second Class Matter, June 29, 1906, at the Postoffice at Chicago, Ill., under Act of March 3, 1879. Acceptance for mailing at special rate of postage provided for in Sec. 1103, Act of Oct. 3, 1917, authorized on June 14, 1918. If undeliverable, forwarding and return postage is guaranteed.

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Council on Physical Therapy.

The Council on Physical Therapy of the American Medical Association has authorized publication of the following article.

H. A. Carter,
Secretary.

ULTRAVIOLET RADIATION USEFUL FOR THERAPEUTIC PURPOSES.

Specification of Minimum Intensity or Radiant Flux: Second Communication.

W. W. Coblentz, Ph.D., D.Sc.
Washington, D. C.

Recently I[1] published the results of a survey of the question of the minimum intensity of ultraviolet radiation acceptable for therapeutic purposes.

Based on six major lines of evidence, I arrived at the conclusion that, in order to insure effective therapeutic results, the intensity (radiant flux density) from sources of heterogeneous ultraviolet radiation, of wavelengths less than and including 313 millimicrons, evaluated according to the spectral erythemic response curve, should not be less than the erythemogenic equivalent of 20 microwatts (200 ergs per second) per square centimeter of homogeneous radiation of the wavelength, of maximum erythemogenic effectiveness, which wavelength, for practical purposes, is taken at the emission line of mercury vapor, at 297 millimicrons (more exactly, 2,967 angstroms).

Using homogeneous radiation of wavelength 297 millimicrons, it may perhaps be possible to cure rickets by exposure to intensities that are lower than 20 microwatts per square centimeter, provided the treatment is sufficiently prolonged. However, such a source is not in common use and, hence, need not be considered.

Although there appears to be no close relationship between the spectral erythemic response and the spectral activation curve of ergosterol in the production of Vitamin

1. Coblentz, W. W.: Ultraviolet Radiation Useful for Therapeutic Purposes, J. A. M. A. 98: 1082 (March 26) 1932.

D and in the healing of rickets, the erythemal reaction is taken as a criterion for judging the effectiveness of the lamp, for three reasons: (a) It is practically the only physiologic reaction that is established with a relatively high degree of accuracy; (b) in the case of exposure to intense sources of ultraviolet radiation, it is a simple and practical means of preventing severe burns, and (c) in the case of weak sources of ultraviolet radiation, it is an efficient safeguard against possible fraudulent sale of lamps that are deficient in ultraviolet radiation.

Furthermore, the preliminary erythema test will no doubt always be made on new subjects, even after the lamp has been standardized by some form of dosage intensity meter. Hence, it seems natural to use the erythemal instead of the antirachitic or a photo-chemical action (the production of vitamin D) as a basis of standardization.

It is to be noted that the specification of a minimum of 20 microwatts per square centimeter is an erythemogenic dosage intensity that appears to meet the average condition as known today; serving, as already stated, as a guide in avoiding burns from overexposure to intense sources of ultraviolet radiation, and eliminating possible fraud in the sale of lamps that do not emit ultraviolet radiation in sufficient intensity to qualify as efficient therapeutic agents. As mentioned in the preceding paper, the ultraviolet radiant flux emitted by the present day "professional models" of the various kinds of therapeutic lamps greatly exceed this specified minimum value.

It is hardly to be expected that this specification will meet all emergencies without supplemental information. For example, suppose that a lamp should be developed, consisting of a high voltage (with condenser) discharge between two electrodes of magnesium, in which most of the ultraviolet radiation is emitted in a single, intense line at about 280 millimicrons. Such a source is well known to physicists.

The emission line of magnesium at 280 millimicrons is in the region of a strong absorption band in ergosterol, which substance has a powerful antirachitic action after exposure to ultraviolet radiation. No data are at hand showing what photochemical action this single emission line would have on the human skin; but it is interesting to note that, because of the low susceptibility of the skin in this

2. Coblentz, W. W.; Stair, R., and Hogue, J. M.: Bur. Stds. J. Research 8: 541 (April) 1932.

spectral region, the erythemal reaction[2] would be relatively weak. On this basis it would therefore appear to be possible to apply a more powerful irradiation from such a lamp without producing a burn than with lamps now in use. Whether such a procedure is desirable is undetermined, though it might be useful in researches on inanimate material. Such sources are now available in the form of cored carbon arcs, which, however, are not so nearly homogeneous in ultraviolet radiation.

A recently introduced source of ultraviolet radiation that requires further physiologic tests is the so-called cold quartz lamp, in which about 95 per cent of the total radiation of wavelengths less than and including 313 millimicrons is emitted in the resonance line of mercury at 254 millimicrons (more exactly, 2,537 angstroms[3]).

The ultraviolet radiant flux,[3] as well as the erythemogenic efficiency of such a lamp is relatively high. Nevertheless, in spite of its high erythemogenic efficiency, further biologic information is needed concerning its effectiveness in healing rickets and in the activation of ergosterol; for, according to published records,[4] when the source of ultraviolet consists of wavelengths longer than 2,750 angstroms, over 60 per cent of ergosterol is converted into vitamin D, whereas, if the lines at 2,537 and 2,654 angstroms are present, only a small amount of ergosterol is converted into vitamin D, after which a further exposure gradually destroys the vitamin D that was formed on first exposure.

As stated in a previous paper,[3] since the publication[4] of experiments on irradiation of cod liver oil, ergosterol and cholesterol, showing that wavelengths shorter than 280 millimicrons are destructive to vitamin D, the feeling is abroad that it is undesirable to use ultraviolet rays of wavelengths shorter than about 280 millimicrons for therapeutic purposes, especially in lamps sold for home use.

---

3. Coblentz, W. W.: Sources of Radiation and Their Physical Characteristics, J. A. M. A. 97: 1965-1967 (Dec 26) 1931.

4. Reerink, E. H., and Van Wijk, A.: Production of Vitamin D, Biochem. J. 23: 1294, 1929. Heilbron, I. M.; Kamm, E. D., and Morton, R. A.: Ibid. 21: 78, 1927; J. Chem. Soc. London 268:2000, 1927. Bills, C. E.; Honeywell, E. M., and Cox, W. M., Jr.: J. Biol. Chem. 80:557 (Dec.) 1928. Wyman, E. T.; Hphnes, A. D.; Smith, L. W.; Stockbarger, D. C., and Pigott, Madeleine G.: Does the Irradiation of Cod Liver Oil Increase Its Antirachitic Potency? Am. J. Dis. Child. 34:753 (Nov.) 1927. Maughan, G. H.: Am. J. Physiol. 87:381 (Dec.) 1928.

The Erythemogenic Unit of Dosage.

The ultraviolet unit of dosage cannot be a concise, tangible specification like a quinine pill. Rather, in a broad sense, the aforementioned specification of 20 microwatts per square centimeter of homogeneous radiation, of the wavelength 297 millimicrons, is analogous to a 1 grain (0.065 Gm.) pill of pure quinine sulphate; and the equivalents of heterogeneous ultraviolet radiation, from various sources, are vaguely analogous to the equivalents that would be specified if, instead of pure quinine sulphate, the material were administered in the form of cinchona bark, or quinine derivatives, of various degrees of purity or concentration.

This analogy is not complete, but it should convey the idea of the difficulties encountered in attempting to standardize ultraviolet dosimetry. For example, the physiologic effect of the pure quinine may perhaps be different from that of cinchona bark. Similarly, the physiologic effect of the homogeneous emission line (297 millimicrons) may be somewhat different from that of the heterogeneous source of ultraviolet radiation. Indeed, differences in the color of the erythema and in the amount of pigmentation produced by different sources are recognized.

However, some sort of standardization is needed in order that workers can compare their results. At present, only in a very general way are experimental results comparable. For example, one worker uses a cadmium photocell standard; others use foot candle, or fluorescent photometer standards; and still others use the mercury lamp as a "high sun standard," with no certainty of constancy of the source.

The unit of dosage of ultraviolet radiation has been discussed by various writers, including myself.[5] The various proponents have dealt with this question from two points of view: viz., the specification of the unit in terms (a) of radiant power in microwatts per square centimeter, and (b) of total energy in ergs per square centimeter. In my previous paper,[1] the ultraviolet unit of dosage was defined in terms of radiant power and, as used, was merely a symbol or an abbreviation to summarize a complex of several variables that enter into the administration of ultraviolet radiation.

5. Coblentz, W. W.: Instruments for Measuring Ultraviolet Radiation and the Unit of Dosage, M. J. & Rec. 130:691 (Dec. 18) 1929.

In the present communication the unit of dosage is specified in terms of the total ultraviolet energy utilized. When followed through to its logical conclusion, the utilization of the total radiant energy, homogeneous radiation of wavelength 297 millimicrons being employed as a standard, appears to be the simplest, the most direct and the most easily reproducible procedure yet tried experimentally.

This specification is based on the results of an extensive investigation[6] in which a comparison was made of the erythema produced by measured amounts of heterogeneous ultraviolet radiation, evaluated by a balanced thermocouple and filter radiometer. In this evaluation, the erythema produced by a measured amount of homogeneous radiation of wavelength 297 millimicrons was used as a standard. In spite of the fact that the sources differed very markedly in ultraviolet spectral energy distribution, a close agreement was obtained between the observed and the calculated exposures, indicating that the radiometric evaluation is reliable. Since such a radiometer is nonselective and can be calibrated in absolute units, it appears to be the most reliable primary standard of comparison we have yet tested.[6]

The following specification, using total energy, instead of radiant power, is merely an amplification of my earlier suggestions[5] of using erythemogenic equivalents, which could not be specific at that time because of the lack of rigidly controlled physical and physiologic (erythemal) measurements, now available.[6] The present specification appears to meet all the requirements that can be foreseen at present. If it does not greatly simplify the manner of recording the experimental data, it will at least introduce a reproducible system that will bring some order out of the present chaos.

In my previous paper[1] (numerical data revised, herewith) it was shown that, for the various sources of heterogeneous ultraviolet radiation of wavelengths less than and including 3,130 angstroms, the erythemogenic equivalent of 20 microwatts per square centimeter of homogeneous radiation of wavelength 2,967 angstroms, in microwatts per square centimeter, is approximately as follows: the sun at

6. Coblentz, W. W.; Stair, R., and Hogue, J. M.: Tests of a Balanced Thermocouple and Filter Radiometer as a Standard Ultraviolet Dosage Intensity Meter. Bur. Stds. J. Research 8:759 (June) 1932. (R. P. No. 450, 10 cents; obtainable only from the Superintendent of Documents, Washington, D. C.)

midday, midsummer, midlatitude, sea level ($20 \div 0.22 =$) 91; the Mazda S-1 lamp, 80; the Mazda S-2 lamp, 93; the high temperature quartz mercury arc, 58; the so-called cold quartz mercury vapor lamp, 36; the carbon arc, 45 to 90 (the latter value is estimated; depending on the electric current, the kind of carbons, and windows), and the Mazda CX tungsten filament lamp 130 (estimated).

Furthermore, in the preceding paper[1] it was shown that it requires about 200,000 ergs per square centimeter of homogeneous radiation, of the wavelength of maximum erythemogenic effectiveness, to produce a minimum perceptible erythema on the average untanned skin. The unit of dosage should therefore be some lower value in order to guard against overexposure.

If we adopt 10,000 ergs (10 kiloergs) per square centimeter of homogeneous radiation of the wavelength 297 millimicrons as the erythemogenic unit of dosage of ultraviolet radiation and call it the Finsen unit (F. U.), then the erythemogenic equivalent dosage of heterogeneous ultraviolet radiation, of wavelengths less than and including 313 millimicrons, emitted by the various aforementioned sources is as follows:

1 F. U. = 10,000 ergs per square centimeter of standard wavelength, 297 millimicron, radiation.
= 45,500 ergs per square centimeter of midday, midlatitude, midsummer, sea level, solar radiation.
= 40,000 ergs per square centimeter of Mazda S-1 lamp radiation.
= 46,500 ergs per square centimeter of Mazda S-2 lamp radiation.
= 29,000 ergs per square centimeter of quartz mercury arc radiation.
= 18,000 ergs per square centimeter of "cold quartz" radiation.
= 22,500 to 45,000 ergs per square centimeter of carbon arc radiation. (The latter value is estimated, depending on the kind of carbon and on the window.)

From the foregoing correlation of the physiologic and the radiometric measurements it will be evident why much of the published data, now available, appears to be inconsistent and may be misleading. The published measurements do not include a factor that equates the erythemal

response. For example, some time ago I was called on to explain why the short wavelength ultraviolet solar radiation, which was relatively large in amount as measured with a photo-electric cell, did not produce an erythema in a much shorter time than a much smaller amount of ultraviolet radiation emitted by a quartz mercury arc lamp. If the experimenter had multiplied the total ultraviolet radiation measurements by the erythemogenic efficiencies of these two sources (not available then; also by a factor for selectivity of his photocell), he would have found a closer agreement in their erythemal effects.

For, as mentioned in a recently published paper,[6] when the factor that equates the physiologic (erythemal) response is taken into consideration there is good agreement between the calculated and the observed times of exposure to produce a minimum perceptible erythema, employing sources differing widely in spectral quality and in total intensity of ultraviolet radiation useful for therapeutic purposes.

Conclusion.

As an illustration of the practical application of the Finsen unit, let us suppose that, from practical experience, it is found that the average person can be given 20 Finsen units daily of Mazda S-2 irradiation without producing an overexposure, and that the particular Mazda S-2 lamp available for use emits a radiant flux of 100 microwatts per square centimeter (1,000 ergs per second) at the standard operating distance. Then, from the described correlations, it follows that 20 Finsen units (46,500 × 20) = 930,000 ergs per square centimeter of Mazda S-2 lamp radiation and hence that an exposure of (930,000 ÷ 1,000 =) 930 seconds, or 15½ minutes daily, is required to produce a minimum perceptible erythema.

If it requires 100 exposures to effect a cure, this will amount to a total of 2,000 Finsen units of Mazda S-2 lamp radiation. This seems simpler than to report the total energy in ergs, which in this instance would amount to 93,000,000 ergs per square centimeter of Mazda S-2 lamp radiation.

2737 Macomb Street, N.W.

Wis. Foundation Exhibit No. T

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A.M.A. SESSION San Francisco — JUNE 13-17, 1938

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Other SAUNDERS BOOKS Described on Page 3

EXHIBIT NO. T.

Prevention of Rickets By Sun Exposure.

To the Editor.—Please advise me with regard to the minimum skin surface that must be exposed to the sun in New York City during July and August, and the minimum length of time for a normal 6 months baby to constitute adequate prophylaxis against rickets. Is there any variation between the white and the Negro?

Henry Laven, M. D., Brooklyn.

Answer.—The simple questions here propounded are difficult to answer exactly. The simplest method of exposure of the skin surface to the sun is that practiced for many years by Rollier in Switzerland. During the late spring months, when the infant can be exposed outdoors, the wrists and ankles are first exposed for short periods and gradually the arms and legs are exposed and then the trunk of the body. Tanning is the sign that ultraviolet radiation has been effective, though of course not all infants will tan, and overexposure may result in sunburn. The answer, therefore, to the minimum skin surface that must be exposed would be starting with the gradual exposure, the maximum amount of skin that could be exposed without harm to the infant. As to the minimum length of time of exposure to the sun for a 6 months baby to insure adequate prophylaxis against rickets, no arbitrary answer can be given. A fair skinned child, who will not tan naturally, cannot be exposed as long as a dark skinned child, who will tan easily. It is said that a Negro will require a longer exposure than fair skinned white children. There are many factors that interfere with the ultraviolet rays of direct sunlight in large cities; fog, haze and city smoke all tend to cut down the effective ultraviolet rays. It is also well to realize that not only the direct sunlight ("direct shine") but also the reflected light of the sun ("sky shine") possesses antirachitic power. The child in the shade receives only sky shine. When placed in the sun, he receives both direct shine and sky shine. To receive all the sky shine possible there must be no obstruction between the child and the dome of the sky. Therefore a child on a narrow street cannot possibly receive as much sky shine as a child in an open park or on an open roof

or balcony. Direct shine, as well as sky shine, is greatest in the middle of the day. Both can produce tan, and the dust and smoke of cities—likewise clouds and fog—will cut down or completely eliminate the ultraviolet rays in each. From experience with a group of infant welfare babies for who only direct exposure to the sun was relied on as prophylaxis against rickets during the summer months, it was found that nearly 50 per cent of the babies showed clinical signs of rickets in September. In cities in the temperate zone, such as New York, it would seem advisable, if possible, to supplement the sunlight with small amounts of additional antirachitic agents in order positively to prevent the development of rickets.

Wis. Foundation Exhibit No. U 543

Clear Days and Hours of Sunshine f

Definition of Clear Days — Days on Wh
From Information Supplied

Elevation Feet	Latitude	City	Jan. Average		Feb. Average		Mar. Average		April Average		May Average	
			Clear Days	Hours of Sunshine	Clear Days	Hours of Sunshine	Clear Days	Hours of Sunshine	Clear Days	Hours of Sunshine	Clear Days	Hours of Sunshine
3730	132	Atlanta, Ga.	10	152	9	160	12	213	11	254	11	264
3945	121	Baltimore	9	147	9	141	10	217	10	227	10	265
3750	140	Birmingham, Ala.	11	147	11	140	12	216	11	241	11	267
3544	149	Boston	9	142	10	149	10	213	9	229	9	269
3299	73	Buffalo	3	93	3	121	5	164	7	209	9	267
3944	119	Chicago	8	132	8	151	8	195	9	236	10	297
3640	112	Cincinnati	7	139	6	143	7	191	9	232	9	269
3804	93	Cleveland	4	108	4	104	6	164	6	207	10	276
3130	113	Dayton	6	124	6	130	8	162	6	221	10	278
5967	130	Denver	11	260	12	291	11	335	9	330	9	271
3355	100	Detroit	6	104	6	133	7	174	8	208	9	262
2770	130	Evanston	10	139	9	142	11	207	10	230	11	264
3980	153	Kansas City	12	170	11	174	11	234	11	234	10	270
5311		Los Angeles		219		211		247		263		271
3665	119	Louisville	8	132	7	144	8	197	9	232	10	270
3415	104	Madison, Wis.	8	127	8	143	8	197	8	214	9	259
3380	111	Milwaukee	8	127	7	134	8	196	9	232	10	276
3531	109	Minneapolis	8	140	9	150	9	209	9	234	9	272
3184	135	New Orleans	9	150	9	159	11	210	11	240	12	260
3640	105	New York	6	134	6	179	9	221	9	241	9	276
3951	172	Oklahoma City	13	175	12	194	13	227	12	243	11	276
2394	88	Pittsburgh	4	95	4	102	6	149	7	189	9	257
2131	93	Portland, Ore.	4	73	4	96	5	147	6	190	7	256
3963	134	Providence, R. I.	10	147	11	169	12	221	10	256	11	276
3697	139	St. Louis	11	169	9	152	10	205	11	233	11	284
3958	140	San Diego	13	215	12	209	14	250	14	268	13	267
3934	146	San Francisco	11	161	11	174	13	232	14	251	13	259
3953	73	Seattle	3	66	3	100	5	142	6	211	9	267
5349	119	Toledo	6	74	6	121	9	170	9	203	11	280
3981	139	Washington, D. C.	9	142	9	163	10	209	11	232	11	271

WISCONSIN ALUMNI
MADISON

...ge U. S. Metropolitan Areas
...Average Cloudiness is 3 or Less.
...U. Weather Bureau.

Wis. Foundation Exhibit No. V

		Clear Days	Hours of Sunshine	Clear Days	Hours of Sunshine	Clear Days	Hours of Sunshine	Clear Days	Hours of Sunshine	Clear Days	Hours of Sunshine	Clear Days	Hours of Sunshine
	260	6	260	9	252	13	241	16	232	13	223	10	160
	262	10	260	10	263	12	241	13	210	10	164	9	142
	299	6	260	9	276	13	227	17	240	15	192	11	136
	290	9	294	11	269	12	222	11	197	9	141	9	136
	304	9	314	9	269	9	214	7	142	3	90	1	85
	319	13	337	13	297	13	239	13	201	8	127	7	113
	334	11	334	12	260	13	261	13	230	9	152	7	117
	362	12	331	11	250	11	224	9	179	4	94	3	87
	307	13	331	11	290	12	248	15	197	9	136	6	102
	330	12	307	11	293	15	265	16	241	15	202	15	149
	292	12	316	12	261	11	229	10	162	6	106	6	91
	309	13	309	13	252	13	234	15	242	13	169	8	127
	316	15	342	15	317	15	259	16	230	13	190	12	155
	302		341		330		296		260		244		228
	299	13	334	13	295	13	254	14	229	10	161	7	119
	294	10	331	11	277	11	230	10	172	7	116	7	108
	307	13	331	13	268	11	234	10	160	7	129	7	110
	301	10	335	11	299	11	213	10	146	7	112	8	111
	296	7	344	7	332	13	285	16	207	13	145	9	142
	317	6	361	6	269	10	239	11	215	9	160	6	143
	311	16	336	17	311	17	273	17	234	10	197	16	174
	265	9	297	10	262	10	231	10	197	6	110	4	94
	301	10	329	10	291	11	194	7	148	4	78	4	62
	296	11	297	11	260	12	227	14	229	11	187	11	142
	304	13	319	14	298	14	268	15	239	11	148	10	134
	301	17	290	17	299	19	270	19	254	16	242	17	226
	335	15	312	13	267	14	262	17	244	14	199	11	187
	283	13	314	13	273	9	165	6	114	3	89	3	88
	291	14	334	14	298	14	224	13	192	7	113	6	97
	275	11	299	11	280	12	251	14	213	10	161	10	143

...RCH FOUNDATION
...ORGAN

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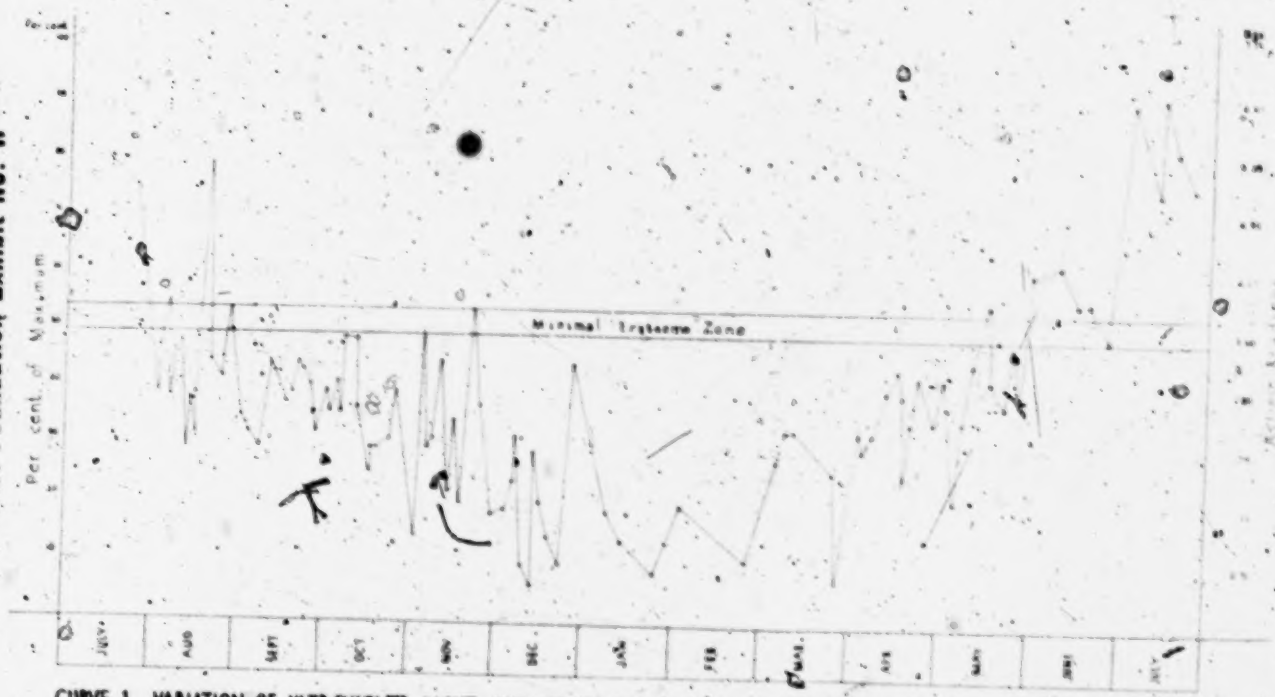
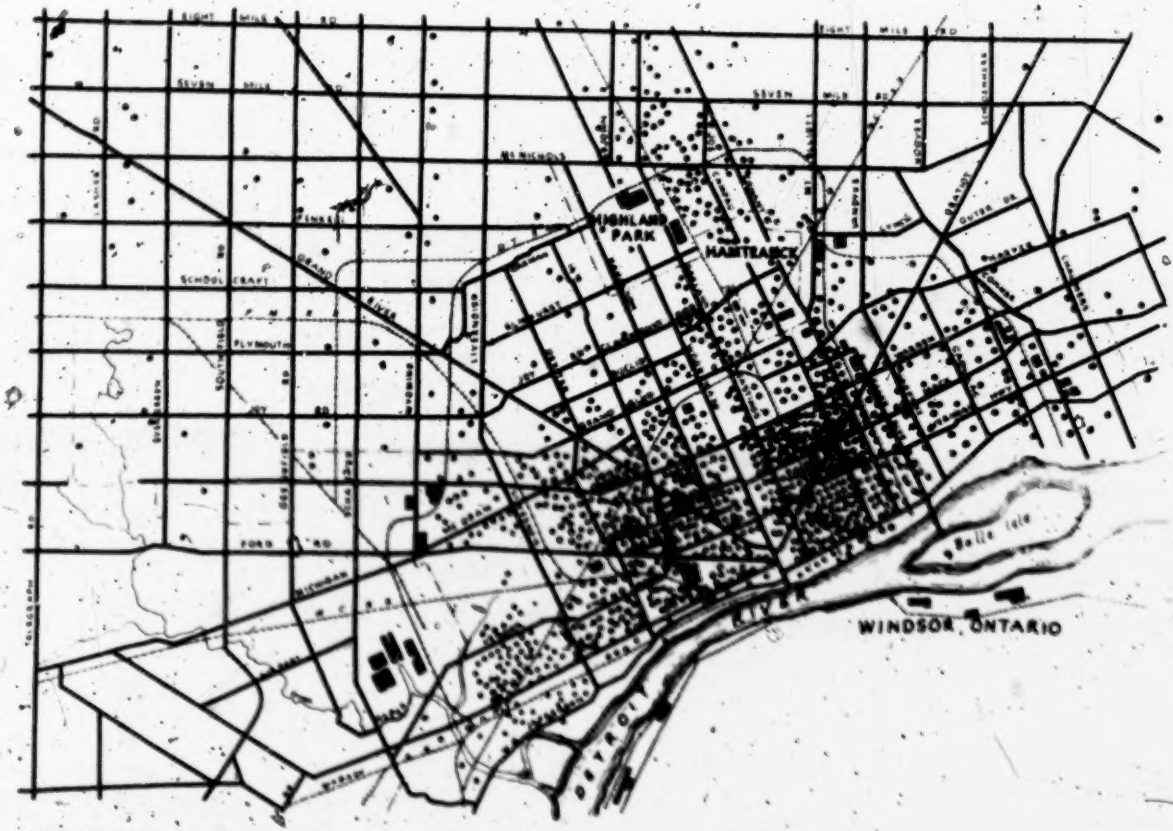
Wis. Foundation Exhibit No. W



CURVE 1 VARIATION OF ULTRAVIOLET LIGHT INDICATED BY ACTINIC MEASUREMENTS FOR THE HOUR 12:00 M TO 1:00 P.M.
CITY OF DETROIT
REF. from ARCHIVES OF PEDIATRICS ... VOL. LVI ... NO. 5 ... MAY 1939

Wis. Foundation Exhibit No. Y



SPOT MAP. SHOWS THE DISTRIBUTION OF CASES ON THE RACHITIC STUDIES THROUGHOUT THE CITY of DETROIT.

REF. from ARCHIVES OF PEDIATRICS ... VOL. LVI .... NO 7 ... JULY 1939

TABLE 1 *Results of previous determinations of settled dust in American cities*

CITY	INVESTIGATOR	LOCATION	YEAR	SEASON OF YEAR	AVERAGE NUMBER OF TONS OF DUST DEPOSITED per SQUARE MILE per YEAR (settled dust)				
					TOTAL	CARBON	ASH	Fe_2O_3	TAR
PITTSBURGH, PA.	MELLON INSTITUTE	WHOLE CITY	1912-13	WHOLE YEAR	1031	317	714	261	10.1
SALT LAKE CITY, UTAH	BUREAU of MINES	do	1919-20	SEPTEMBER - APRIL	349	122	227	.....	.....
GRAFTON, W. VA.	do	WHOLE TOWN	1922	APRIL - DECEMBER	1876	871	1005		
CLEVELAND, OHIO	HEALTH COUNCIL	WHOLE CITY	1927-29	WHOLE YEAR	780	228	552	120	
BALTIMORE, MD.	HEALTH DEPT.	CENTER CITY	1928-29	MARCH 1926 & OCTOBER 1928	1.800	990	810		8.7
DO	do	3 MILES from CENTER	1928-29	do	800				
DO	do	10 MILES from CENTER	1928-29	do	340				

REF. U.S. TREASURY DEPT. PUBLIC HEALTH BULLETIN No. 224 P. 7

Wis. Foundation Exhibit No. AA

551

BLE XII. - *Average number of condensation nuclei in a cubic centimeter of Air for each city, for each Trip, & for all Trips*

CITY	NUMBER OF OBSERVATIONS AND AVERAGE NUMBER OF NUCLEI									
	TRIP I 6/8/31 – 12/4/31		TRIP II 12/11/31 – 4/29/32		TRIP III 5/17/32 – 9/14/32		TRIP IV 11/2/32 – 3/8/33		ALL TRIPS 6/8/31 – 3/8/33	
	NUMBER OF OBSERVATIONS	AVERAGE NUMBER OF NUCLEI IN THOUSANDS	NUMBER OF OBSERVATIONS	AVERAGE NUMBER OF NUCLEI IN THOUSANDS	NUMBER OF OBSERVATIONS	AVERAGE NUMBER OF NUCLEI IN THOUSANDS	NUMBER OF OBSERVATIONS	AVERAGE NUMBER OF NUCLEI IN THOUSANDS	NUMBER OF OBSERVATIONS	AVERAGE NUMBER OF NUCLEI IN THOUSANDS
ASHINGTON	16	108	15	142	12	106	13	133	53	122
ALTIMORE	14	145	11	188	12	242	12	181	49	187
HILADELPHIA	10	212	15	227	12	201	12	249	49	223
EW YORK	12	207	11	318	12	229	12	310	47	265
OSTON	16	183	11	212	12	250	12	282	51	226
UFFALO	8	69	12	266	12	77	11	111	42	140
ITTSBURGH	11	100	14	175	12	154	18	170	55	154
LEVELAND	15	98	12	116	15	93	15	202	57	128
ETROIT	15	181	12	175	12	150	12	178	51	172
HICAGO	12	221	17	260	12	390	12	252	53	279
T. LOUIS	15	231	15	304	15	249	12	191	57	246
EW ORLEANS	14	118	12	112	12	86	15	164	53	122
OS ANGELES	15	172	11	151	12	124	15	272	53	185
AN FRANCISCO	15	155	14	143	17	166	15	207	61	168

1 10 INDEPENDANT COUNTS WERE MADE FOR EACH OBSERVATION

Ref. U.S. TREASURY DEPT. PUBLIC HEALTH BULLETIN #233, P. 30

Wis. Foundation Exhibit No. BB

EXHIBIT CC.

University of Wisconsin
College of Agriculture
Madison, Wisconsin

Department of Bioehemistry

October 25, 1940.

Federal Security Agency
Washington, D. C.

Attention Mr. Alanson W. Willcox, Presiding Officer
Flour Hearing, Docket #FDG-21.

Dear Sir:

With regard to the optional ingredients which are to be permitted in Flour and in Farina, I wish to make the following comments which are relevant:

It has long been known that whole cereal grains are high in total phosphorus. Correspondingly, with this knowledge there has developed the assumption that a diet high in cereals provided an adequate amount of this element. This, however, is now known to be a fallacious assumption especially in the case of manufactured cereals which have been freed from most of the outer layers of the seed which contain most of the phosphorus. The fallacy of the assumption arose through the fact that 50-70% of the phosphorus in cereals is present as phytic acid which is poorly available. This lack of availability can be corrected by the addition of suitable amounts of vitamin D. These findings which represent a recent development in the chemistry of nutrition reveal that vitamin D is more beneficial in its action in connection with cereals than with any other known source of phosphorus. Formerly, it was believed that milk and its products constituted the best vehicle for bringing adequate supplies of vitamin D to the public. We now know that while this is probably true in connection with the nutrition of children, vitamin D is not nearly so necessary for the assimilation of the phosphorus of milk as it is for the phosphorus of the cereal diet. In addition cereals are consumed by practically all individuals in large quantities, the amount of which unlike medicinal agents is definitely limited by bulk and caloric content. Accordingly, a fair

amount of vitamin D introduced into all cereal products would probably do as much to make vitamin D available to the public as fortification of milk with this essential. To my mind as long as the public will insist upon the consumption of highly milled cereals the necessity for the use of additional amounts of vitamin D will be emphatically evident.

Very truly yours,
Harry Steenbock,
Harry Steenbock, Ph.D.

State of Wisconsin, } ss.
County of Dane. }

I, Harry Steenbock, being first duly sworn on oath; depose and say: that I have read the above and foregoing statement, signed by me; that I have knowledge of the facts, and that I believe the facts above set forth are true.

Harry Steenbock,
Harry Steenbock.

Subscribed and sworn to before me this 25th day of October, A. D. 1940.

Grace Roum,
(Seal) *Notary Public.*

My commission expires June 27, 1943.

EXHIBIT NO. EE.

Cream of Wheat.

November 15, 1940.

Mr. Allison Wilcox,
Room 3106, South Building,
Department of Agriculture,
Independence Avenue, 12th and 14th Streets,
Washington, D. C.

Dear Mr. Wilcox:

I testified on Tuesday, November twelfth, at the hearings concerned with standards of identity of flour. During cross-examination, the attorney representing the government requested that I state what quantities of nutritional substances should be allowed as minima and maxima, in

flour. At my request and with the consent of everyone present, you are allowing me to submit my answers to this question by mail.

During my direct testimony and during cross-examination, I made the statement that I thought that all substances which are found in wheat should be allowed as ingredients of flour. For the purposes of the regulations, however, it is apparently necessary that the Food and Drug Administration require that these ingredients be allowed only in excess of certain minima which the Administration will promulgate. In view of this, it perhaps is advisable that only ingredients of greater importance be allowed as either regular or optional ingredients at this time. It is my opinion, therefore, that thiamine, nicotinic acid, iron, and calcium be made regular ingredients, that riboflavin be made an optional ingredient, and that flour be considered as not the proper vehicle for enrichment with vitamin A, vitamin C and vitamin D. The following suggestions for minimum and maximum standards are based upon the dietary needs of the public.

I have read all of the literature which seems to have a bearing on this problem, and have conferred with scores of scientists, nutritionists, and home economists, and as a result of this study, I am of the opinion that flour should contain a minimum of 550 I. U. of thiamine per pound and a maximum of about 775 I. U. per pound. This maximum is 50 percent above the minimum and it is my opinion that it is not in the public interest to allow flour to contain more than this maximum limit.

Unfortunately, there is not available enough riboflavin to allow enrichment of flour to a level which I consider to be proper. Therefore, it seems desirable that the addition of riboflavin to flour be considered as optional and that this addition be changed from optional to regular just as soon as supplies of this important vitamin have accumulated to take care of the demands which will be made by the milling industry in complying with this provision. It is my opinion that flour should contain 1.22 mgs. per pound as a minimum and that the maximum should be about 1.83 mgs. per pound. Again this maximum level is 50 per cent above the minimum. Although there would be little harm in allowing larger quantities of riboflavin to be added, it would not be in the interest of the public.

It is my opinion that nicotinic acid be considered a regular ingredient of flour and that flour be required to con-

tain a minimum of 6.15 mgs. of nicotinic acid (or nicotinic acid amide) per pound and a maximum of 10 mgs. of nicotinic acid (or nicotinic acid amide) per pound.

It is my opinion that iron should be made a regular ingredient of flour and that flour contain a minimum of 6.15 mgs. per pound and a maximum of 10 mgs. per pound. It is not in the interest of the consumer to allow flour to contain an amount exceeding this maximum.

It is my opinion that calcium should be proclaimed a regular ingredient of flour and that it should contain a minimum of 492 mgs. per pound and a maximum of 2,000 mgs. per pound. This maximum figure is suggested so that it will not be less than the amounts of calcium that are contained in self-rising flours which are now being sold.

It is my feeling that from the point of view of the public, it does not matter whether the minimum levels are obtained by retention, by altered milling procedures, or by the addition of natural or synthetic substances. Therefore, I feel that there is no necessity for a separate standard for lightly milled flour. Should a separate standard be set up for lightly milled flour, it is my opinion that it should be identical to that for long milled flour. Furthermore, since there is no evidence that synthetic vitamin preparations are in any way inferior to natural vitamin substances, it is not in the interest of the public to allow a distinction to be made between flours, the potencies of which are attained by synthetic or natural vitamin substances.

In answer to the specific request of the government's attorney, therefore, I make the following proposal:

	Per pound of flour Minimum	Maximum
Regular ingredients		
Vitamin B_1	350 I.U.	775 I.U.
Nicotinic acid (or amide)	6.15 mgs.	10 mgs.
Iron	6.15 mgs.	10 mgs.
Calcium	492 mgs.	2000 mgs.
Optional ingredients		
Riboflavin	1.22 mgs.	1.83 mgs.

Cordially yours,

/S/ Robert S. Harris,
Assistant Professor of Nutritional Biochemistry.

RSH:GH

Federal Security Agency

Food and Drug Administration

[Docket No. F.D.C.-21]

In the Matter of a Definition and Standard of Identity for Each of the Following Foods: (A) Flour, White Flour, Wheat Flour, Plain Flour; (B) Enriched Flour; (C) Bromated Flour; (D) Enriched Bromated Flour; (E) Durum Flour; (F) Self-Rising Flour, Self-Rising White Flour, Self-Rising Wheat Flour; (G) Enriched Self-Rising Flour; (H) Whole Wheat Flour, Graham Flour, Entire Wheat Flour; (I) Bromated Whole Wheat Flour; (J) Whole Durum Wheat Flour; (K) Crushed Wheat, Coarse Ground Wheat; (L) Cracked Wheat; (M) Farina; (N) Enriched Farina; (O) Semolina.

Report of Presiding Officer.

To the Federal Security Administrator:

Pursuant to order dated August 1, 1940, public hearings were held on September 9, 10, 11, 12, 13, 14, 16 and 17, and November 12, 13, 14, 15 and 16, 1940, for the purpose of receiving evidence upon the basis of which regulations might be promulgated establishing definitions and standards of identity for flour and certain related wheat products. There are submitted herewith proposed findings of fact and conclusions, and a proposal order, with the recommendation that they be published in accordance with the applicable regulations. (5 Fed. Reg. 2381, § 2.712). There is submitted, also, a copy of the record on which the proposals are based.

Many provisions of the original proposal which accompanied the order of August 1 were not challenged, while many other provisions have been modified in accordance with the recommendations made by interested parties. Those provisions in regard to which there appears to be no longer any substantial difference of opinion will not be discussed in this report. The principal evidence in support of them is cited in the record references appended to the proposed findings of fact.

6. Proposals for the additions of vitamins and minerals to flour, bromated flour, phosphated flour, self-rising flour

and farina occupied a considerable part of the original hearing and were the principal subject of the adjourned hearing. Numerous optional ingredients were recommended, but in the main the recommendations were cumulative rather than conflicting.

There is no dispute about the underlying facts. Flour is one of the principal foods in the United States, the average daily consumption of 6½ ounces representing something like one quarter of the ordinary energy requirements. While individual consumption undoubtedly varies widely from this average, it is generally agreed that the lower income groups consume more flour per capita than do others.

It is also generally accepted that there are today serious deficiencies of certain vitamins and minerals in the diets of large groups of the population, and that the lower income groups suffer most seriously in this regard. Among the most important are deficiencies of elements of the vitamin B complex and of iron. A lack of calcium also exists in certain portions of the population, although there is not complete unanimity in regard to the extent or importance of this deficiency. In the case of vitamin D, a widespread deficiency among infants and young children is generally recognized, but the need for additional vitamin D among adults is disputed.

Whole wheat is a rich source of elements of the vitamin B complex and also of iron, but these elements are largely removed in the milling of white flour. Nutritionists have long advocated greater consumption of whole wheat products, largely for the purpose of supplying these elements in the diet. They have recommended milk, on the other hand, as a natural source of calcium and as an appropriate carrier for vitamin D.

There was substantial agreement among the witnesses, both specific and lay, that the foregoing elements are suitable for addition to flour, bromated flour, phosphated flour, self-rising flour, and farina; and by the close of the hearings there was reasonably full agreement upon the quantities of these ingredients appropriate for this purpose. While other elements were also recommended, namely vitamins A, B_6, C, and E, pantothenic acid and phosphorous, these proposals have not been pressed except as some of these elements (notably phosphorous) may incidentally accompany the elements for which nutritional claims would be recognized.

It was also generally agreed that a program of enrichment should be subject to strict regulation. Thus, Dr. W. H. Strowd, who as the secretary of the Soft Wheat Millers Association was one of the chief industry spokesmen, testified (R. p. 332):

> "In other words, fortification should take place under strict regulations. As far as I am personally concerned, my interest in this would have remained academic had it not been for the understanding that under this new Food & Drug Act there would be strict regulations to safeguard the interests of the consumer, as well as to protect the honest producer against dishonest competition."

Other witnesses developed more fully the objections, from the consumer standpoint, to allowing enrichment of flour with any one or any combination of the nutritive elements in question. Thus, Miss Charlotte Chatfield, testifying on behalf of the Bureau of Home Economic of the Department of Agriculture, said (R. pp. 710-712):

> "It would be against consumer interests to allow too much latitude in the kinds and quantities of added nutrients. Such a product deserves a separate standard. Any standard for white flour that allows the optional addition of one or a dozen of these nutrients would not promote honesty and fair dealing in the interests of the consumer. Such a standard would tend to confuse consumers and the fortified product might seem to them to be a short cut to a balanced diet.
>
> "Nutritionists do not subscribe to the idea that there is any easy road to obtaining a good diet. Most nutritionists would oppose creating a standard for a multiplicity of kinds of supplemented flours, each of which was unstandardized and independent of all the rest. It would lead to advertising abuses; advertising claims would tend to be accepted too credulously by some and rather completely discounted by others."
>
> . . . . . .
>
> "It would not be in line with the suggestion that I attempted to make, to permit of all of the permutations and combinations. One muanufacturer supplies one mineral and another one supplies another; and certain others supply one or another vitamin. And if each of those is called 'fortified flour,' it would be extremely confusing."

Dr. Robert R. Williams testified (R. pp. 1688-1689):

"It would seem to me desirable that this flour should receive some form of distinctive name, because an essential part of our problem is that of the education of the public, with regard to the value of this reform, at least it is a reform as I construe it, and if there is a great diversity of products sold under a great diversity of names and with a great diversity of formulas, then the public is going to be merely confused by the changes, and probably wind up by taking the old-fashioned flour instead of seeking the product that would actually lead to better nutrition on their part."

A practical demonstration of the validity of these opinions is suggested by the fact that, although all artificial enrichment of cereal products is of recent origin, the products which were on the market at the time of the hearings and concerning which testimony was given were:

Flours, phosphated flours, and self-rising flours—

1. One with added vitamin D (R. pp. 396, 399);
2. One with added calcium (R. p. 839);
3. One with added vitamin B_1, nicotinic acid and calcium (R. p. 335);
4. One with added vitamin B_1, calcium and iron (R. p. 630);
5. One containing wheat germ and wheat germ oil, said to furnish vitamin B_1, vitamin E and riboflavin (R. p. 386);
6. One "long extraction" flour containing vitamin B_1, riboflavin, calcium and iron (R. p. 504);

Farinas—

7. One with added vitamin D (R. p. 399);
8. One with added vitamin B_1, calcium and iron (R. pp. 1421-1422).

In the case of item 3, some 23 mills were using the same formula, but each of the other items was apparently produced by only one company. With the exception of items 1 and 7, and items 2 and 8, no two of these products contained the same combination of nutritive ingredients, and in a number of instances two products contained no single element in common.

While the record does not show the claims made on behalf of these various commodities in advertising and labeling, it seems self-evident that even wholly honest state-

ments in regard to products so diverse must prove confusing to all but the most well-informed of consumers. The fear of honest producers that in the absence of strict regulation they will face dishonest competition also appears justified.

It is submitted that the following proposed finding is fully warranted by the record:

> "36. There have recently been placed on the market flours and self-rising flours enriched with one or more of the nutritional elements referred to above. These flours vary widely in composition. Unless a standard is promulgated which limits the kinds and amounts of enrichment, the manufacturers' selection of the various nutritive elements and combinations of elements on the basis of economic and merchandising considerations is likely to lead to a great increase in the diversity, both qualitative and quantitative, in enriched flours offered to the public. Such diversity would tend to confuse and mislead consumers as to the relative value of and need for the several nutritional elements, and would impede rather than promote honesty and fair dealing in the interest of consumers."

To meet this situation the proposed regulation would permit none of these elements as optional ingredients in flour, bromated flour, phosphated flour, self-rising flour or farina, but would establish separate identities for "enriched flour," "enriched bromated flour," "enriched self-rising flour," and "enriched farina," each of which would be required to contain vitamin B_1, riboflavin, nicotinic acid and iron, and in each of which vitamin D and calcium would be optional ingredients.*

Although there were some differences of opinion, and some shifts of opinion during the course of the hearings, the nutritionists who testified arrived at substantially complete agreement upon the desirability of establishing the definitions and standards of identity thus outlined; with the exception that, solely because of supposed difficulties of procurement, they recommended that until riboflavin becomes available in sufficient quantities it be made an optional rather than a required ingredient. Inasmuch as the only witness with first hand knowledge of the subject (whose testimony was given after that of the nutritionists

* As monocalcium phosphate would be an optional ingredient in "enriched flour," there is no occasion to establish a separate identity for "enriched phosphated flour."

referred to) stated that production of riboflavin could be expended "fairly rapidly" to "keep pace with what the industry may require" (R. p. 1823), it appears that by the time the proposed regulation becomes effective this difficulty will have been overcome.

With the same reservation concerning riboflavin, the proposal in its broader outlines has been accepted by the Millers National Federation in its brief, despite the Federation's earlier recommendation that vitamin B_1 be made the only required ingredient in an enriched flour. The Federation, however, coupled its acceptance with a recommendation that another standard be created for a flour with any one or more of the nutritive ingredients added, in order that "specification products" might be sold—for example, to an institution or to the army.

The reasonableness of the proposed regulation must be considered in the light of the burden which it would impose upon dealings in unstandardized foods that would contain some added nutritive ingredients but would fail to comply with the requirements for "enriched flour." A miller desiring to sell such a product would face the same kind of difficulty referred to above in connection with low-grade soft wheat products, in that he could not legally ship such a product in interstate commerce if it purported to be, or was represented as, either "flour" or "enriched flour." Here, again, it is doubtful under what circumstances a special designation, such as "partially enriched flour," would obviate the difficulty in the case of the "specification products" referred to in the brief of the Millers National Federation.

The finding of fact recommended above, that great diversity in the enrichment of flours would tend to confuse and mislead consumers, would in itself appear sufficient, under the provisions of section 401 of the Act, to warrant the promulgation of a regulation designed to lessen the diversity and to hold it within such bounds as to facilitate consumer understanding. In substantiation of this conclusion, however, and as indicating the reasonableness of the selection of vitamin B_1, riboflavin, nicotinic acid and iron as the required ingredients in "enriched flour," consideration should be given to several other facts established by the record.

As stated above, deficiencies of these four elements are widespread and serious. The importance of supplementing the dietary with them is at least more uniformly recog-

nized, and probably is greater, than in the case of other nutritive elements suitable for addition to flour.

These elements being present in whole wheat, moreover, consumers have to some extent been educated to look to cereal products to supply them.

Deficiencies of vitamin B_1, riboflavin and nicotinic acid are likely to occur in the same individuals. Dr. Russell Wilder, for example, testified as follows (R. p. 1604):

> "Q. Is it true, that the existence of a diet deficiency disease, manifestations of which are the symptoms of beriberi, for instance, would likely be accompanied by other diet deficiency diseases, such as pellagra, or scurvy, when the diet is insufficient to such an extent as to cause one diet deficiency disease, is it true that other diet deficiencies are likely to exist?
>
> "A. That is absolutely true. It is practically impossible to find a single dietary deficiency in clinical practice, one has to go to the extreme elaborateness of such an experiment as I described at the last hearing, to see a pure thiamin deficiency, for instance."

This view was supported with respect to the low-income groups by Dr. W. H. Strowd (R. p. 1742). Dr. William H. Sebrell, Jr., also testified to the existence of multiple deficiency diseases. (R. p. 1638).

This fact alone goes far to justify as reasonable the requirement of grouping these three vitamins, on the same principle which justifies the establishment of a minimum limit for a single ingredient—that honesty and fair dealing would not be served by an enrichment which does not make some substantial contribution toward meeting the needs of consumers.

It may be objected that to be reasonable a standard must be sufficiently flexible to enable millers to sell enriched flours adapted to the needs of different individuals or different groups of the population. One answer to such a contention is found in Dr. Wilder's testimony that deficiencies do not occur singly. What is perhaps a more basic answer is also established by the record.

As Dr. Robert S. Harris pointed out (R. pp. 1508-1511), in a general nutritional program it is possible to deal with people only in the mass and not as individuals. Individual needs may vary widely, and he suggested that if average needs are the basis of calculation, a figure perhaps 50 per cent above the average be used, in order to allow for the

greater requirements in individual cases. But the questions involved here, he stated, cannot be approached as a doctor would approach the nutritional problem of a particular patient.

The record does not indicate any such differences in the incidence of these deficiencies in different areas as would warrant providing alternative standards with a view to the needs of different parts of the country. Dr. Wilder testified that nicotinic acid deficiency, while it is most prevalent in the South, is by no means confined to that region. (R. pp. 1609-1610). There was no suggestion that lack of vitamin B_1, of riboflavin or of iron is to any extent whatever a regional problem. Whether deficiencies of vitamin D and calcium are equally widespread need not be considered, since it is recommended that they be made optional rather than required ingredients of "enriched flour."

In view of these facts, it is believed that the record establishes the reasonableness of the proposed regulation even though it should effectively prevent the sale of partially enriched flours.

ERRATA—Federal Register April 1, 1941.

P. 1730, column 3, line 12: the word "flash" should be "flask".

P. 1731, column 1, line 17: the figure "869" should be "868".

P. 1733, column 1, line 10 under item 69: the figure "384" should be "584".

P. 1733, column 3, line 3 under item 82: the word "and" appearing at the end of this line should be "now".

P. 1734, column 1, line 3 under item 88: the word "brand" should be "bran".

P. 1734, column 3, line 27: the word "or" should be "of".

P. 1737, column 1, line 4: the figure "300" should be "500".

P. 1737, column 1, line 6: the figure "6" should be "8".

FEDERAL SECURITY AGENCY.

Filed Mar. 29, 1941.

Food and Drug Administration.

[Docket No. F.D.C.-21]

In the Matter of a Definition and Standard of Indemnity for Each of the Following Foods: (A) Flour, White Flour, Wheat Flour, Plain Flour; (B) Enriched Flour; (C) Bromated Flour; (D) Enriched Bromated Flour; (E) Durum Flour; (F) Self-Rising Flour, Self-Rising White Flour, Self-Rising Wheat Flour; (G) Enriched Self-Rising Flour; (H) Whole Wheat Flour, Graham Flour, Entire Wheat Flour; (I) Bromated Whole Wheat Flour; (J) Whole Durum Wheat Flour; (K) Crushed Wheat, Coarse Ground Wheat; (L) Cracked Wheat; (M) Farina; (N) Enriched Farina; (O) Semolina.

Proposed Order.

It is proposed that, by virtue of the authority vested in the Federal Security Administrator by the provisions of section 401 of the Federal Food, Drug, and Cosmetic Act, 52 Stat. 1046, 21 U.S.C. sec. 341 (Supp. V, 1939); of the Reorganization Act of 1939, 53 Stat. 561, ff., 5 U.S.C. sec. 133-133r (Supp. V., 1939); and Reorganization Plans No. I (53 Stat. 1423, 4 F.R. 2727), and No. IV (54 Stat. —, 5 F.R. 2421), and upon the basis of the evidence received at the hearing in the above-entitled matter, duly held pursuant to notice thereof dated August 1, 1940, issued by the Acting Federal Security Administrator, the following facts be found and the promulgation of the regulations hereinafter set forth be ordered:

Proposed Findings of Fact.

1. The food commonly and usually known as "flour", "white flour", "wheat flour", or "plain flour" is manufactured from wheat, both hard and soft, other than durum wheat and red durum wheat. (R. pp. 51, 54.)

2. Flour is used primarily for making white bread and biscuit, and consumers of flour normally expect that it

will be suitable for these purposes. (R. pp. 60-61, 64, 119-120, 669-670, 690.)

3. In making flour the wheat is first cleaned. It is usually tempered. It is then ground and bolted so at to separate the inner portion of the wheat berry, known as the endosperm, from the outer portion, known as the bran coat, or from both bran coat and germ. Flour consists essentially of finely ground endosperm. In the milling process the separation of bran coat and germ from endosperm is never complete, but a certain degree of separation is necessary to produce flour which will make acceptable white bread and biscuit. (R. pp. 54-56, 116, 119, 1532-1535.)

4. Where all the flour milled from the wheat used is combined without separation into grades, the flour is called "straight flour." That portion which is most nearly free of bran coat and germ is frequently taken off and sold as "patent flour". The remaining portion, which contains more bran coat and germ than straight flour, is known as "clear flour". (R. pp. 55-56, 121.)

5. "Straight flours" will make acceptable white bread and biscuit. As the degree of removal of bran coat and germ is lessened, flours become progressively less desirable for such purposes until so much bran coat and germ remain that acceptable white bread and biscuit cannot be made. However, such products are suitable for other food uses and are usually sold under such designations as "low-grade flour" and "second clear flour". Products containing even more bran coat and germ are sold usually as animal feed. (R. pp. 61, 65-73, 167-169, 215-220, 1542-1544.)

6. A reasonably accurate criterion of the degree of separation of bran coat, or bran coat and germ, from endosperm is the ash content of the flour, since the ash content of the bran coat is some 20 to 25 times that of the endosperm and the ash content of the germ some 10 to 15 times that of the endosperm. (R. pp. 58, 61-62, 203.)

7. In general, a limit on ash content can be used to distinguish between flours which will make acceptable white bread and biscuit and those which will not, but the limit is not the same for high protein flours (hard wheat flours) and low protein flours (soft wheat flours). In high protein flours, particularly those used for bread making, a

somewhat lesser degree of separation is acceptable than in low protein flours. (R. pp. 62-63, 121-122.)

8. In most straight flours the percent of ash is not more than one-twentieth of the percent of protein and is usually somewhat less. (R. pp. 65, 121, 134-135.)

9. Increased amounts of bran coat and germ which increase the percent of ash to a point where it exceeds that of straight flour by more than 0.3 result in products which will not make acceptable white bread or biscuit. Products containing more ash than one-twentieth of the protein plus 0.3 percent are not generally sold in the household trade and are not generally used to make white bread or biscuit. (R. pp. 64-73, 121, 143, 170, 214-215, 721-735.)

10. A maximum ash limit of one-twentieth of the protein plus 0.3 percent will distinguish reasonably effectively between flour suitable for making white bread and biscuits and products not suitable for those purposes. (R. pp. 64-73, 121, 170, 214-215, 721-735)

11. Variation in the moisture content of flour after manufacture causes variations in the percent of protein and ash. The effect of such variations can be eliminated by calculating the percent of protein and ash to a moisture free basis. When such calculation is made the figure 0.35 would be the approximate equivalent of, and should be substituted for, the figure 0.3 in findings 9 and 10. (R. pp. 174-184, 543, 607-608, 723-726; Exh. A)

12. All fluor contains some moisture. Excessive moisture, however, impairs the keeping quality of flour and unnecessarily increases its weight. A reasonable limit for moisture, which is not exceeded in good milling practice, is .15 percent. (R. pp. 77-78)

13. Flour is a finely ground product and the degree of fineness is a distinguishing characteristic of flour. Such fineness is secured in good milling practice by bolting the flour through a cloth having openings not larger than those of woven wire cloth designated "149 micron (No. 100)" in table I of "Standard Specifications for Sieves," published March 1, 1940, in L. C. 584 of the U. S. Department of Commerce, National Bureau of Standards. (R. pp. 55, 116-119, 130-131, 681)

14. Malted wheat is sometimes mixed with wheat used for making flour, or malted wheat flour or malted barley flour is sometimes added to flour, in small amounts so as

to compensate for natural deficiencies of enzymes necessary for bread making. A reasonable maximum limit for materials so added is 0.5 percent. (R. pp. 58, 60, 96-97, 140-141, 150-151, 193, 195-197, 200, 256-258)

15. A satisfactory and reliable method for the determination of ash content of flour is that prescribed in the book "Official and Tentative Methods of Analysis of the Association of Official Agricultural Chemists", 4th edition, 1935, page 207, under the caption "Method I—Official". This method has recently been republished in the book "Official and Tentative Methods of Analysis of the Association of Official Agricultural Chemists", 5th edition, 1940, page 212, under the caption "Method I—Official". This method is well known and widely used when examining flour for its ash content. (R. pp. 74-75)

16. A satisfactory and reliable method for determination of moisture in flour is that prescribed in the book "Official and Tentative Methods of Analysis of the Association of Official Agricultural Chemists", 4th edition, 1935, page 206, under the caption "Vacuum Oven Method—Official". The same method has recently been republished in the book "Official and Tentative Methods of Analysis of the Association of Official Agricultural Chemists", 5th edition, 1940, page 211, under the caption "Vacuum Oven Method—Official". This method is well-known and widely used when examining flour for its moisture content. (R. p. 78)

17. The protein content of flour is ordinarily calculated from the nitrogen content of the flour by multiplying the nitrogen content by 5.7. A satisfactory and reliable chemical method for determination of nitrogen is that prescribed in the book "Official and Tentative Methods of Analysis of the Association of Official Agricultural Chemists", 4th edition, 1935, page 25, under the caption "Kjeldahl-Gunning-Arnold Method—Official". The same method has been recently republished in the book "Official and Tentative Methods of Analysis of the Association of Official Agricultural Chemists", 5th edition, 1940, page 26, under the caption "Kjeldahl-Gunning-Arnold Method—Official". This method is well known and widely used for determining nitrogen in flour. (R. p. 76)

18. Flour as first prepared is slightly colored by the natural coloring in the wheat. It is a common practice in

the milling industry to bleach the flour by treating it with one or more of the following bleaches or bleaching agents:

(1) Oxides of nitrogen,
(2) Chlorine,
(3) Nitrosyl chloride,
(4) Nitrogen trichloride,
(5) Benzoyl peroxide in a carrier consisting of either potassium alum and magnesium carbonate, or a mixture of calcium sulphate and magnesium carbonate; the weight of the carrier being in no case more than five times that of the benzoyl peroxide. (R. pp. 80-81, 122-123, 228-229, 237-238, 315-316)

19. Besides the bleaching effect, chlorine, nitrosyl chloride, and nitrogen trichloride have an artificial aging effect on the flour so treated. Only enough of the bleaching agent or agents to accomplish such desired effects is used. Excessive quantities impair the flour. (R. pp. 81, 122-124, 228-229)

20. Flour so bleached is whiter than freshly milled unbleached flour, but is similar in color to unbleached flour naturally aged. Since about 1920 it has been prevailing trade practice to label flours treated with bleaching agents as "bleached". Many consumers have come to distinguish between bleached and unbleached flour, and are familiar with and understand the word "bleached" as applied to flour. The word "bleached", as so applied, has become the common name of the ingredients added to the flour through the bleaching process. (R. pp. 81-84, 123-125, 230)

21. Some flour of high protein content, to which small amounts of potassium bromate have been added, can be made into dough which is easier to handle and which produces loaves of greater volume than dough made from the same flour to which no potassium bromate has been added. Addition of potassium bromate to flour has been practiced on a small scale, but the practice is increasing. Flour to which potassium bromate has been added is labeled "bromated" and sold exclusively to bakers. The name "bromated flour" is commonly and usually applied to differentiate this product from flour. (R. pp. 252-254, 261-266, 268-269, 288-290, 303, 624)

22. The amount of potassium bromate added depends on the properties of flour to which it is added, and varies in different crop years. The amount ordinarily used does not exceed 40 parts per million in domestic trade, or 75 parts

per million in export trade. An excess of potassium bromate in dough has undesirable effects on bread. A reasonable minimum protein content of the flour used in making bromated flour is 13.5 percent. (R. pp. 267-268, 270-272, 281, 296, 302-304, 308-312, 619, 621, 626)

23. The food commonly and usually known as "self-rising flour", "self-rising white flour", or "self-rising wheat flour", is prepared by intimately mixing flour, a leavening agent, and salt for seasoning. (R. pp. 791-792, 828-829, 861-862)

24. The leavening agent usually consists of a mixture of sodium bicarbonate and monocalcium phosphate. Sodium acid pyrophosphate, an acid salt of somewhat less neutralizing value that monocalcium phosphate, is sometimes substituted for monocalcium phosphate. (R. pp. 792, 806, 894-895, 898-900, 1865-1867)

25. When self-rising flour is used in baking, carbon dioxide gas is evolved through the chemical reaction of the sodium bicarbonate and the acid leavening ingredient. The gas so evolved leavens or raises the dough giving the baked product one of its characteristic qualities. To accomplish this satisfactorily a certain minimum amount of carbondioxide must be evolved. The amount of carbon dioxide gas which will be effective for the purpose of proper leavening is not less than 0.5 percent of the weight of the self-rising flour. (R. pp. 793, 795-796, 812-813, 826, 932; Exh. J)

26. To avoid discoloration and other undesired characteristics in the baked product, the amounts of sodium bicarbonate and acid leavening ingredient must be so proportioned that no sodium bicarbonate remains unacted upon in the baked product. Unnecessarily large amounts of the leavening substances leave objectionable quantities of residues in the baked product. A reasonable maximum limit for the leavening agents in self-rising flour is four and one-half parts to each hundred parts of flour. (R. pp. 362, 793, 796, 810, 814-816, 829, 862-864, 867)

27. A satisfactory and reasonably accurate method for determining the amount of carbon dioxide evolved from self-rising flour is the method prescribed in "Official and Tentative Methods of Analysis of the Association of Official Agricultural Chemists", 5th edition, 1940, beginning on page 186 under "Gasometric Method with Chittick's Apparatus—Official", except that the following procedure is

substituted for the procedure specified therein under "6—Determination":

Weigh 17 grams of the official sample into flask A, add 15-20 glass beads (4-6 mm. diameter) and connect this flask with the apparatus (fig. 22). Open stopcock C and by means of the leveling bulb E bring the displacement solution to the 25 cc. graduation above the zero mark. (This 25 cc. is a partial allowance for the volume of acid to be used in the decomposition.) Allow the apparatus to stand 1-2 minutes to insure that the temperature and pressure within the apparatus are the same as those of the room. Close the stopcock, lower the leveling bulb somewhat to reduce the pressure within the apparatus, and slowly run into the decomposition flask from burette F 45 cc. of sulfuric acid (1 + 5). To prevent the liberated carbon dioxide from escaping through the acid burette into the air, keep the displacement solution in the leveling bulb at all times during the decomposition at a lower level than that in the gas-measuring tube. Rotate and then vigorously agitate the decomposition flask for three minutes to mix the contents intimately. Allow to stand for ten minutes to bring to equilibrium. Equalize the pressure in the measuring tube by means of the leveling bulb and read the volume of gas from the zero point on the tube. Deduct 20 cc. from this reading (this 20 cc. together with previous allowance of 25 cc. compensates for the 45 cc. acid used in the decomposition). Observe the temperature of the air surrounding the apparatus and also the barometric pressure and multiply the number of cc. of gas evolved by the factor given in Table 24—Chapter XLIII for the temperature and pressure observed. Divide the corrected reading by 100 to obtain the apparent percent by weight of carbon dioxide in the official sample.

Correct the apparent percent of carbon dioxide to compensate for varying atmospheric conditions by immediately assaying a synthetic sample by the same method in the same apparatus.

Prepare the synthetic sample with 16.2 grams of flour, 0.30 gram of monocalcium phosphate, 0.30 gram of salt, and a sufficient quantity of sodium bicarbonate U. S. P. (dried over sulfuric acid) to yield the amount of carbon dioxide recovered in assay of official sample. Determine this quantity by multiplying weight of carbon dioxide recovered in assay of official sample by 1.91.

Divide the weight of carbon dioxide recovered from synthetic sample by weight of carbon dioxide contained in sodium bicarbonate used.

Divide the quotient into the apparent percent of carbon dioxide in official sample to obtain percent carbon dioxide evolved from the official sample. (R. pp. 794-795, 811-812, 880)

28. There has recently been placed on the market a self-rising flour containing, in addition to the usual ingredients and in partial substitution for sodium bicarbonate, small amounts of calcium carbonate and light magnesium carbonate. Calcium carbonate and light magnesium carbonate react slowly with the acid ingredient when this self-rising flour is used in baking, but the reaction is incomplete and some calcium carbonate and light magnesium carbonate remain unchanged in the baked product. (R. pp. 839, 845, 869, 1312, 1325, 1328-1330, 1353)

29. The reason for adding the calcium carbonate is to enrich the diet in calcium and to increase the ratio of calcium to phosphorus. The reason alleged for adding the light magnesium carbonate is that it tends to preserve in the self-rising flour the fluffiness and free flowing qualities characteristic of freshly milled flour. (R. pp. 840-842, 845-846, 1275, 1278-1280, 1295, 1313-1315, 1326-1328, 1889-1890, 1902)

30. The probable effects of diversity of enrichment of self-rising flour, and of indiscriminate enrichment of foods, are set forth in findings 36 and 37. The amount used in this self-rising flour, 0.176 percent, and in amounts up to 0.5 percent light magnesium carbonate causes no observable change in fluffiness, free flowing qualities, or other properties of the self-rising flour. (R. pp. 1903-1906, 1907-1909, 1913, 1915-1916)

31. The flour used in preparing self-rising flour is ordinarily bleached prior to mixing with leavening agents and salt. Sometimes the bleaching agent containing benzoyl peroxide, described in finding 18, is mixed with the flour along with the leavening agents and salt. Findings 18, 19, and 20 apply also to self-rising flour. (R. pp. 792-793, 797-799, 832)

32. Flour and self-rising flour are among the principal items of food of the people of the United States. The average consumption is about six and one-half ounces per person per day. This six and one-half ounces supplies about

one-fourth of the normal energy requirements of the average person. (R. pp. 483, 755, 1515-1516, 1600, 1633)

33. Recent investigations of the diets of persons in various sections and in various income groups have shown that in many cases the food consumed does not furnish sufficient amounts of certain necessary nutritional elements to maintain health. The deficiencies are more prevalent in the case of persons with low incomes. Such persons usually supply a larger part of their energy requirements from flour and self-rising flour than the average person because of their cheapness as a source of energy. (R. pp. 329-331, 488-498, 754, 1433-1434, 1609-1613, 1632-1633, 1640-1642, 1659-1660, 1683)

34. Among the most serious and widespread deficiencies are those of vitamin B_1, riboflavin, nicotinic acid, and iron. Deficiencies of these vitamins tend to occur in the same individuals. (R. pp. 346-347, 492-497, 1421, 1429, 1454-1455, 1604-1638, 1642)

35. A deficiency of calcium exists in certain groups of the population. A deficiency of vitamin D exists in large numbers of infants and children. (R. pp. 402-407, 410-413, 557, 1315-1324, 1350-1352, 1424-1425, 1607, 1644, 1728-1732; exh. DD)

36. There have recently been placed on the market flours and self-rising flours enriched with one or more of the nutritional elements referred to above. These flours vary widely in composition. Unless a standard is promulgated which limits the kinds and amounts of enrichment, the manufacturers' selection of the various nutritive elements and combinations of elements on the basis of economic and merchandising considerations is likely to lead to a great increase in the diversity, both qualitative and quantitative, in enriched flours offered to the public. Such diversity would tend to confuse and mislead consumers as to the relative value of and need for the several nutritional elements, and would impede rather than promote honesty and fair dealing in the interest of consumers. (R. pp. 349, 481-482, 524, 630-631, 824-825, 1643, 1688-1689, 1954)

37. In general, indiscriminate enrichment of foods (including flour and self-rising flour) with vitamins and minerals would tend to confuse and mislead consumers by giving rise to conflicting claims regarding the beneficial effects of such substances, and would be likely to lead to the impression on the part of consumers that a single

article of food so enriched would meet all nutritional needs. (R. pp. 332, 445-446, 452, 469-470, 708-711, 1929, 1955)

38. Limited enrichment of selected staple foods, on the other hand, is readily adapted to the promotion of consumer understanding of the relative value of enriched and natural foods, utilizing such education as consumers have received regarding the nutritive value of natural foods. (R. pp. 331-333, 446-448, 451-453, 524, 709-711, 1633, 1679-1682, 1929-1930, 1958-1959)

39. Essential food elements, now present only in insufficient quantities in many diets, which are present in wheat in considerable quantity, are vitamins of the B complex and compounds of iron. At the present time the following vitamins of the B complex are available for the enrichment of flour and self-rising flour, either in the form of synthetic products or secured from wheat by slight changes in the process of milling flour,—vitamin B_1, riboflavin, nicotinic acid or nicotinic acid amide. (R. pp. 346, 455-458, 484-487, 498-499, 511, 592-594, 760-763, 1530, 1604, 1822-1823, 1930)

40. Vitamin D and calcium are now used singly to a limited extent in the enrichment of flour and self-rising flour. Consumer education has generally recommended dairy products as the most desirable source of calcium, and milk as the product most suitable for enrichment with vitamin D in the light of known deficiencies of this element. The addition, however, of vitamin D and calcium as optional ingredients to an enriched flour or enriched self-rising flour will serve a useful purpose for the benefit of persons who do not consume sufficient dairy products. (R. pp. 347, 396-398, 403, 1275, 1504-1505, 1592, 1605-1606, 1609, 1645-1646, 1708, 1714-1716, 1724, 1741; Exh. X, Exh. Y, Exh. Z, Exh. CC)

41. Enrichment of flour or self-rising flour with vitamin A or vitamin C would be unsatisfactory for the reason, among others, that these vitamins are likely to decompose in flour. (R. pp. 433, 447-448, 461-462, 759-760, 1594, 1635, 1661, 1687)

42. Stabilized wheat germ oil has been proposed as an optional ingredient of flour for the purpose of increasing the vitamin E content of the flour and for its flavor. The need for the enrichment of foods with vitamin E has not been established. The evidence does not establish that wheat germ oil or stabilized wheat germ oil, in the quantity

proposed, has an appreciable effect on the flavor. (R. pp. 386-387, 392, 462, 485, 601-603, 758-759, 1457)

43. Pending experience with the use of enriched flour and enriched self-rising flour, consumer education and understanding will be facilitated by restricting the enrichment, not only with respect to the ingredients to be added, but also by the fixing of minimum and maximum amounts of such ingredients. Reasonable limits for this purpose are, for each pound of flour or self-rising flour: not less than 1.66 milligrams nor more than 2.5 milligrams of vitamin B_1, not less than 1.2 milligrams nor more than 1.8 milligrams of riboflavin, not less than 6 milligrams nor more than 9 milligrams of nicotinic acid or nicotinic acid amide, not less than 6 milligrams nor more than 24 milligrams of iron (Fe), not less than 250 U. S. P. units nor more than 1000 U. S. P. units of vitamin D, and not less than 500 milligrams nor more than 2000 milligrams of calcium (Ca.) (R. pp. 333-334, 453, 524, 711-713, 752-757, 1380, 1591-1597, 1600-1601, 1613-1615, 1624-1625, 1633-1640, 1660-1665, 1683-1684, 1799, 1801-1802, 1940-1941, 1954)

44. Wheat germ, in its natural form or processed to remove part of its oil, is suitable ingredient for furnishing a part of the requirements for vitamin B_1, riboflavin, nicotinic acid, and iron, but amounts greater than 5 percent in flour or self-rising flour impair the color of the baked product and make it difficult to produce acceptable bread. (R. pp. 347-348, 355-356, 758, 776-777, 1435, 1529, 1556-1559, 1581, 1621)

45. Iron has been added to flour in the form of harmless and assimilable salts (other harmless and assimilable forms of iron would serve as well). Various harmless and assimilable salts of calcium, such as the phosphates, have been used. The use of any of the calcium phosphates results in the introduction of phosphorus in addition to that naturally present in flour, but such introduction is harmless and is thought by some persons to be desirable. Vitamin D has been added to flour as a concentrate of vitamin D in a food oil. When vitamins and iron are added to flour or self-rising flour, their bulk is so small that the use of a carrier facilitates their intimate and uniform admixture with the flour. (R. pp. 363-364, 367, 416-421, 594-598, 763, 766, 1625-1626)

46. Vitamin B_1 in flour and self-rising flour is subject to some loss during baking; the degree of loss increases as the dough decreases in acidity or becomes alkaline.

The danger of loss is great when consumers use soda in making. The addition of monocalcium phosphate safeguards against such losses. (R. pp. 341-344, 365, 580, 1700)

47. Flour and self-rising flour enriched with vitamins and minerals have not acquired common or usual names; accurate designations for these products are "enriched flour" and "enriched self-rising flour". (R. pp. 465, 756, 1942)

48. The reasons for enriching flour with vitamins and minerals are equally applicable to bromated flour. Bromated flour so enriched has not acquired a common or usual name; an accurate designation for this product is "enriched bromated flour". (R. pp. 1406, 1408, 1582-1584, 1769)

49. The food commonly and usually known as "durum flour" is manufactured from durum wheat. Durum flour is not ordinarily used for making bread or biscuit but is used for making macaroni and noodles. The purchaser of durum flour expects that it will be suitable for these purposes. (R. pp. 1197-1199)

50. Except as above stated the method of preparation of durum flour is the same as that described in finding 3 with respect to flour. Finding 6 is applicable to durum flour. (R. pp. 1197, 1202-1203)

51. The characteristics of durum wheat do not vary to an extent comparable to the variation between hard and soft wheats used for making flour, and a fixed ash limit is satisfactory for distinguishing between durum flours which will make acceptable macaroni and noodles and those which will not. A reasonable ash limit is 1.3 percent, or 1.5 percent when calculated to a moisture free basis. (R. pp. 1200-1202, 1213, 1218, 1221)

52. Findings 12, 13, 15, and 16 are applicable to durum flour. (R. pp. 1198, 1203-1204)

53. A food is prepared and widely sold in certain parts of the United States consisting of a mixture of flour and monocalcium phosphate, sometimes with the addition of dicalcium phosphate. (R. pp. 960-961, 982-984)

54. The primary reason for adding the monocalcium phosphate is to have an excess of acid reacting material in the dough when such flour is used with soda and sour milk for making biscuit. Dicalcium phosphate also increases the acid reacting material, but it is far less effective for this purpose than monocalcium phosphate, and the primary reason for adding it is to enrich the diet in

calcium. The probable effects of diversity of enrichment of flour, and of indiscriminate enrichment of foods, are set forth in findings 36 and 37. (R. pp. 976-977, 981-983)

55. Small amounts of monocalcium phosphate will not accomplish the purpose of such addition; too much is likely to impart an undesirable acid taste to products made from such flour. Reasonable limits for monocalcium phosphate are a minimum of 0.25 percent and a maximum of 0.75 percent of the phosphated flour. (R. pp. 964, 969, 983-984)

56. Flour to which monocalcium phosphate has been added is commonly labeled "flour—Calcium Phosphate Added". The names "Phosphated flour", "phosphated white flour", and "phosphated wheat flour" are commonly and usually applied to differentiate this product from flour. (R. pp. 961, 968, 975)

57. The flour used in preparing phosphated flour is ordinarily bleached prior to mixing with the monocalcium phosphate. Sometimes the bleaching agent containing benzoyl peroxide, described in finding 18, is mixed with the flour along with the monocalcium phosphate. Findings 18, 19, and 20 apply also to phosphated flour. (R. pp. 963-965)

58. The three foods commonly and usually known as (1) "whole wheat flour", "graham flour", or "entire wheat flour"; (2) "cracked wheat"; (3) "crushed wheat" or "coarse ground wheat", are all made by grinding, cracking or crushing wheat other than durum wheat or red durum wheat. Consumers generally expect these foods to contain the constituents of the whole wheat berry, other than moisture, in their natural proportions, although in some cases some of the finer material (largely endosperm and germ) or the coarser material (largely bran) is removed, the product often being labeled to show such removal. (R. pp. 1045-1046, 1052, 1061, 1062, 1064, 1067, 1097, 1127, 1132-1133, 1164-1166, 1172, 1976, 1968-1969, 1984, 1987)

59. In the manufacture of these foods the wheat is first cleaned, and is sometimes tempered. Each of these foods contains some moisture. Excessive moisture, however, impairs the keeping qualities and unreasonably increases the weight of these foods. A reasonable limit for moisture, which is not exceeded in good manufacturing practice, is 15 percent. (R. pp. 1048, 1050-1051, 1053, 1131, 1171)

60. Food products made from the entire wheat berry vary widely in the size of particles. They also vary in the

character and shape of the particles, depending on whether the products are made by a grinding or crushing process or by a cracking or cutting process. A ground or crushed product, even though coarsely ground, contains a substantial amount of fine particles. A cracked or cut product, although it may contain some fine particles, consists chiefly of angular fragments of substantially uniform size. (R. pp. 1048-1049, 1102-1104, 1110, 1128, 1147)

61. The most finely ground of these products is commonly and usually known as "whole wheat flour", "graham flour", or "entire wheat flour". This product is commonly used for making whole wheat bread, and the purchaser expects it to be suitable for that purpose. (R. pp. 1045, 1052, 1053, 1055, 1061, 1097-1099)

62. In order to make whole wheat bread, whole wheat flour must be of a certain degree of fineness. A reasonable limit to the degree of fineness for this purpose is that at least 90 percent of the whole wheat flour pass through a No. 8 sieve and at least 50 percent of it pass through a No. 20 sieve. Most, though not all, products now sold under the name "whole wheat flour" comply with such a limitation. (R. pp. 1049, 1054-1055, 1058, 1060, 1066, 1113-1115, 1985)

63. Malted wheat is sometimes mixed with wheat used for making whole wheat flour, or malted wheat flour or malted barley flour is sometimes added to the whole wheat flour, in small amounts so as to compensate for natural deficiencies of enzymes necessary for bread making. A reasonable maximum limit is 0.5 percent. (R. pp. 1069, 1073-1075; Exh. L)

64. In the process of milling of whole wheat flour, the particles of endosperm sometimes are separated from the ground particles of bran coat and germ of the wheat, and subsequently recombined. In such cases the particles of endosperm are sometimes treated with nitrogen trichloride, chlorine, or a mixture of nitrosyl chloride and chlorine to obtain bleaching and artificial aging effects. Only enough of these agents is used to bring about these effects. Whole wheat flour so treated is labeled "bleached". (R. pp. 1045, 1068, 1076-1079, 1081)

65. Products coarser than whole wheat flour, while not suitable for use as the primary ingredient in making bread, are used with flour or whole wheat flour to make special kinds of bread, often designated "cracked wheat bread" and "crushed wheat bread". They are also used to some

extent as breakfast foods or an ingredient of certain breakfast foods. In order to be suitable for these purposes the products must be of a certain degree of fineness. (R. pp. 1047, 1055, 1071-1073, 1087, 1164-1166)

66. Products made by the cracking or cutting process have a different appearance and different texture from those made by the grinding or crushing process. But considerable confusion now exists in regard to nomenclature of these products, with the result that purchasers of them or of bread containing them are likely to have difficulty in knowing what they are purchasing. Thus, the name "cracked wheat", while it is generally applied to products made by the cracking or cutting process, is also applied occasionally to coarsely ground food products of wheat. The name "cracked wheat" is also applied to animal feed which differs in several respects from products sold for human food, being made up mostly of broken or cracked wheat berries. The fineness of these food products is important in determining their suitability for the purposes stated in finding 65, and the degree of fineness and of uniformity in the size of particles affords a reasonable method (in addition to the difference in method of manufacture and in shape and character of particles) of differentiating between them. (R. pp. 1105-1106, 1127-1130, 1144-1148, 1969)

67. The coarse product made by the grinding process or crushing process is usually sold under the name "crushed wheat", and sometimes as "rolled wheat", or "curled wheat", and occasionally as "cracked wheat". The term "coarse ground wheat" has also been proposed. A reasonable limit on the sizes of the particles of this product, which is suitable for the purposes stated in finding 65, is that at least 40 percent will pass through a No. 8 sieve, but less than 50 percent will pass through a No. 20 sieve. (R. pp. 1164-1165, 1974, 1986)

68. The coarse product made by the cracking or cutting process is commonly known as "cracked wheat". A reasonable limit on the size of the particles of this product, which is suitable for the purposes stated in finding 65, is that at least 90 percent will pass through a No. 8 sieve and not more than 20 percent will pass through a No. 20 sieve. (R. pp. 1126, 1138, 1047-1048, 1142, 1973, 1983-1984)

69. A suitable procedure for determining the percentage of these foods which will be retained on or pass through No. 8 and No. 20 sieves is as follows:

Use No. 8 and No. 20 sieves, having standard 8 inch full height frames, complying with the specifications for wire cloth and sieve frames in "Standard Specifications for Sieves" published March 1, 1940, in L. C. 384 of the U. S. Department of Commerce, National Bureau of Standards. Fit a No. 8 sieve into a No. 20 sieve. Attach bottom pan to the No. 20 sieve. Pour 100 grams of the sample into the No. 8 sieve. Attach cover and hold the assembly in a slightly inclined position with one hand. Shake the sieves by striking the sides against the other hand with an upward stroke, at the rate of about 150 times per minute. Turn the sieves about one-sixth of a revolution, each time in the same direction, after each 25 strokes. Continue shaking for two minutes. Weigh the material which fails to pass through the No. 8 sieve and the material which passes through the No. 20 sieve. (R. pp. 1049, 1130, 1168-1169)

70. A satisfactory and reliable method for the determination of moisture in whole wheat flour is that referred to in finding 16. This method is well known and widely used in examining whole wheat flour for its moisture content. (R. p. 1051)

71. A satisfactory and reliable method for the determination of moisture in cracked wheat and crushed wheat is that prescribed in the book "Official and Tentative Methods of Analysis of the Association of Official Agricultural Chemists", 4th edition, 1935, page 335, under the caption "Preparation of Sample—Official" and "Moisture I. Drying with Heat—Official". The same method has recently been republished in the book "Official and Tentative Methods of Analysis of the Association of Official Agricultural Chemists", 5th edition, 1940, page 353, under "Preparation of Sample — Official" and "Moisture I. Drying with Heat—Official". This method is well known and widely used in examining crushed wheat and cracked wheat for their moisture content. (R. p. 1132)

72. The reasons for adding potassium bromate to flour, and the amounts in which it is added, stated in findings 21 and 22, are equally applicable to whole wheat flour. Whole wheat flour to which potassium bromate is added is labeled "bromated"; an accurate designation for the product is "bromated whole wheat flour". (R. pp. 1069, 1090-1094; Exh. M)

73. The food known as "whole durum wheat flour" is prepared from durum wheat by the same process employed

in making whole wheat flour (findings 59, 62, 63, 64, and 65), and is used in making certain kinds of bread. Consumers generally expect whole durum wheat flour to contain the constituents of the whole durum wheat berry, other than moisture, in their natural proportions. A reasonable moisture limit and reasonable granulation limits for whole durum wheat flour are the same as for whole wheat flour. (R. pp. 1224-1226, 1229)

74. The food commonly and usually known as "farina" is manufactured from wheat, either hard or soft, other than durum wheat and red durum wheat. (R. pp. 1001-1008)

75. In making farina the wheat is first cleaned. It is usually tempered. It is then ground, bran coat and germ are separated from the endosperm, and the flour is removed by bolting. Farine consists essentially of endosperm, but the particles of farina are larger than those of flour. The size of the particles of farina has become well established through usage; and is a distinguishing characteristic of the product. The size is such that farina will pass through a No. 20 sieve but that only a small amount will pass through a No. 100 sieve. The material passing through the No. 100 sieve comes mostly from abrasion of particles of farina during handling after it is manufactured. A reasonable limit for this fine material is 3.0 percent. (R. pp. 1002, 1004-1005, 1015, 1038-1039)

76. A satisfactory method for testing farina for size of particles is as follows:

Use No. 20 and No. 100 sieves, having standard 8 inch full height frames, complying with the specifications for wire cloth and sieve frames in "Standard Specifications for Sieves", published March 1, 1940, in L. C. 584 of the U. S. Department of Commerce, National Bureau of Standards. Fit a No. 20 sieve into a No. 100 sieve. Attach bottom pan to the No. 100 sieve. Pour 100 grams of the sample into the No. 20 sieve. Attach cover and hold the assembly in a slightly inclined position with one hand. Shake the sieves by striking the sides against the other hand with an upward stroke, at the rate of about 150 times per minute. Turn the sieves about one-sixth of a revolution, each time in the same direction, after each 25 strokes. Continue shaking for two minutes. Weigh the material which fails to pass through the No. 20 sieve and the material which passes through the No. 100 sieve. (R. pp. 1004-1005)

77. Consumers generally expect farina to be almost entirely free from bran coat and germ. In this respect it corresponds substantially to "patent flour." The extent of removal can be measured by the percent of ash in the farina (see finding 6). A generally recognized and reasonable maximum limit for ash is about 0.5 percent, or not more than 0.6 percent on a moisture-free basis. (R. pp. 1006-1007, 1034, 1037)

78. All farina contains some moisture. Excessive moisture impairs the keeping qualities of farina and unnecessarily increases its weight. A reasonable limit for moisture, which is not exceeded in good milling practice, is 15 percent. (R. pp. 1008-1009)

79. A satisfactory and reliable method for the determination of ash content of farina is that referred to in finding 15. A satisfactory and reliable method for the determination of moisture content of farina is that referred to in finding 16. These methods are well known and widely used. (R. pp. 1007-1008)

80. The removal of bran coat and germ from endosperm in the manufacture of farina removes those parts of the wheat which are richest in vitamins and minerals. (R. pp. 1421, 1424, 1428, 1433, 1434, 1441)

81. Farina is used as a breakfast food and as an ingredient of macaroni products. It is not widely consumed as flour, but it is extensively used as a cereal food for children and in many cases is the only cereal food used during a period of their growth. (R. pp. 1003, 1014, 1022-1023, 1441-1442, 1474-1475)

82. Certain manufacturers are now selling farina to which have been added vitamins and minerals. Ingredients and being added for this purpose are vitamin D in the form of irradiated yeast (other sources of vitamin D would serve equally well), and portions of the vitamin B complex and minerals in the form of freshly milled wheat germ or wheat germ from which part of the oil has been removed. Iron and calcium have also been added in the form of assimilable salts. In addition to wheat germ other sources of members of the vitamin B complex are available. (R. pp. 1023-1024, 1421-1422, 1425, 1429-1432)

83. In general, the interest of consumers is affected by the enrichment of farina with vitamins and minerals in the same way as has been outlined in connection with the enrichment of flour in findings 34 to 43, inclusive. (R. pp. 1021-1022, 1029, 1426-1427, 1704)

84. Because of the small quantities in which farina is ordinarily consumed and because of its special use in diets of some children there is occasion for the enrichment of farina with quantities of vitamins and minerals substantially in excess of the reasonable maxima for flour. Findings 44 and 45 are applicable to farina, except that farina is not used for making bread and a reasonable limit for the wheat germ is 8 percent. (R. pp. 1032, 1435-1437, 1443-1444, 1502)

85. The time necessary for cooking enriched farina can be shortened by the addition of from one-half to one percent of disodium phosphate. (R. pp. 1422-1423, 1463-1465, 1493-1494)

86. Farina enriched with vitamins and minerals has not acquired a common or usual name; an accurate designation for the product is "enriched farina". (R. pp. 465, 756, 1023, 1942)

87. The food commonly and usually known as semolina is manufactured from durum wheat. (R. pp. 1231-1232, 1248)

88. In making semolina the wheat is first cleaned. It is usually tempered. It is then ground, the brand coat and germ are separated from the endosperm, and durum flour is removed by bolting. Semolina consists essentially of the endosperm, but the particles of semolina are larger than those of durum flour. The size of the particles of semolina has become well established through usage, and is a distinguishing characteristic of the product. The size is such that semolina will pass through a No. 20 sieve but that only a small amount will pass through a No. 100 sieve. The material passing through the No. 100 sieve comes mostly from abrasion of particles of semolina during handling after it is manufactured. A reasonable limit for this fine material is 3.0 percent. (R. pp. 1232, 1234, 1247)

89. A satisfactory method for testing semolina for size of particles is the method described in finding 76. (R. pp. 1233, 1242)

90. Semolina is used in the manufacture of macaroni and noodles, and sometimes as a breakfast food. Consumers generally expect semolina to be almost entirely free from bran coat and germ. The extent of the removal can be measured by the percent of ash in the semolina (see findings 6). A generally recognized and reasonable limit for ash is about 0.8 percent or not more than 0.9 percent on a moisture-free basis. (R. pp. 1233-1235, 1242, 1254)

91. All semolina contains some moisture. Excessive moisture impairs the keeping qualities of semolina and unnecessarily increases its weight. A reasonable limit for moisture, which is not exceeded in good manufacturing practice, is 15 percent. (R. pp. 1235-1236)

92. A satisfactory and reliable method for the determination of the ash content of semolina is that referred to in finding 15. A satisfactory and reliable method for determination of the moisture content of semolina is that referred to in finding 16. These methods are well known and widely used. (R. pp. 1235-1236)

On the basis of the foregoing proposed findings of fact it is concluded that the promulgation of regulations fixing and establishing each of the following definitions and standards of identity for the several food products will promote honesty and fair dealing in the interest of consumers:

Proposed Regulations.

§ 15.000 Flour, white flour, wheat flour, plain flour—identity; Label statement of optional ingredients. (a) Flour, white flour, wheat flour, plain flour, is the food prepared by grinding and bolting cleaned wheat other than durum wheat and red durum wheat; to compensate for any natural deficiency of enzymes, malted wheat, malted wheat flour, malted barley flour, or any combination of two or more of these, may be used in a quantity not more than 0.5 percent. One of the cloths through which the flour is bolted has openings not larger than those of woven wire cloth designated "149 micron (No. 100)" in table I of "Standard Specifications for Sieves", published March 1, 1940, in L. C. 584 of the U. S. Department of Commerce, National Bureau of Standards. The flour is freed from bran coat, or bran coat and germ, to such extent that the percent of ash therein, calculated to a moisture-free basis, is not more than the sum of one-twentieth of the percent of protein therein, calculated to a moisture-free basis, and 0.35. Its moisture content is not more than 15 percent. Unless such addition conceals damage or inferiority of the flour or makes it appear better or of greater value than it is, one or any combination of two or more of the following optional bleaching ingredients may be added in a quantity not more than sufficient for bleaching, or in case such ingredient has an artificial aging effect, in a quantity

not more than sufficient for bleaching and such artificial aging effect:

(1) oxides of nitrogen,
(2) chlorine,
(3) nitrosyl chloride,
(4) nitrogen trichloride,
(5) one part by weight of benzoyl peroxide mixed with not more than five parts by weight of a mixture of either potassium alum or calcium sulphate and magnesium carbonate.

(b) When any optional bleaching ingredient is used, the label shall bear the word "Bleached". Wherever the name of the food appears on the label so conspicuously as to be easily seen under customary conditions of purchase, the word "Bleached" shall immediately and conspicuously precede or follow such name without intervening written, printed, or graphic matter; except that where such name is a part of a trade-mark or brand, other written, printed, or graphic matter, which is also a part of such trade-mark or brand, may so intervene if the word "Bleached" is in such juxtaposition with such trade-mark or brand as to be conspicuously related to such name.

(c) For the purposes of this section—

(1) Ash is determined by the method prescribed in the book "Official and Tentative Methods of Analysis of the Association of Official Agricultural Chemists", 5th edition, 1940, page 212, under "Method I—Official." Ash is calculated to a moisture-free basis by subtracting the percent of moisture in the flour from 100, dividing the remainder into the percent of ash, and multiplying the quotient by 100.

(2) Protein is 5.7 times the nitrogen as determined by method prescribed in such book on page 26, under "Kjeldahl-Gunning-Arnold Method—Official." Protein is calculated to a moisture-free basis by substracting the percent of moisture in the flour from 100, dividing the remainder into the percent or protein, and multiplying the quotient by 100.

(3) Moisture is determined by the method prescribed in such book on page 211, under "Vacuum Oven Method—Official."

§ 15.010 Enriched flour—identity; Label statement of optional ingredients. Enriched flour conforms to the definition and standard of identity, and is subject to the re-

quirements for label statement of optional ingredients, prescribed for flour by § 15.000, except that—

(1) it contains in each pound not less than 1.66 milligrams and not more than 2.5 milligrams of vitamin B_1, not less than 1.2 milligrams and not more than 1.8 milligrams of riboflavin, not less than 6 milligrams and not more than 9 milligrams of nicotinic acid or nicotinic acid amide, not less than 6 milligrams and not more than 24 milligrams of iron (Fe);

(2) vitamin D may be added in such quantity that each pound of the finished enriched flour contains not less than 250 U. S. P. units and not more than 1,000 U. S. P. units of vitamin D;

(3) calcium may be added in such quantity that each pound of the finished enriched flour contains not less than 500 milligrams and not more than 2,000 milligrams of calcium (Ca), except that it may be acidified with monocalcium phosphate irrespective of the minimum limit for calcium (Ca) herein prescribed;

(4) it may contain not more than 5 percent by weight of wheat germ or partly defatted wheat germ; and

(5) in determining whether the ash content complies with the requirements of this regulation allowance is made for any added minerals.

Iron may be added only in a form which is harmless and assimilable; calcium only in the form of monocalcium phosphate, dicalcium phosphate or tricalcium phosphate, or any mixture of two or all of these. The substances referred to in clauses (1) and (2) may be added in a harmless carrier which does not impair the enriched flour; such carrier is used only in the quantity necessary to effect an intimate and uniform admixture of such substances with the flour.

§ 15.020 Bromated flour—Identity; Label statement of optional ingredients. Bromated flour conforms to the definition and standard of identity, and is subject to the requirements for label statement of optional ingredients prescribed for flour by § 15.000, except that —

(1) potassium bromate is added in a quantity not exceeding 75 parts to each million parts of the finished bromated flour; and

(2) its protein contents is not less than 13.5 percent.

§ 15.030 Enriched bromated flour—Identity; Label statement of optional ingredients. Enriched bromated flour conforms to the definition and standard of identity, and

is subject to the requirements for label statement of optional ingredients, prescribed for enriched flour by § 15.010, except that——

(1) potassium bromate is added in a quantity not exceeding 75 parts to each million parts of the finished enriched bromated flour; and

(2) its protein content is not less than 13.5 percent.

§ 15.040 Durum flour—Identity. (a) Durum flour is the food prepared by grinding and bolting cleaned durum wheat. One of the cloths through which such flour is bolted has openings not larger than those of woven wire cloth designated "149 micron (No. 100)" in table I of "Standard Specifications for Sieves," published March 1, 1940, in L. C. 384 of the U. S. Department of Commerce, National Bureau of Standards. It is freed from bran coat, or bran coat and germ, to such extent that the percent of ash therein, calculated to a moisture-free basis, is not more than 1.5 percent. Its moisture content is not more than 15 percent.

(b) For the purposes of this section, ash and moisture are determined by the methods therefor referred to in § 15.000 (e).

§ 15.050 Self-rising flour, self-rising white flour, self-rising wheat flour—Identity; Label statement of optional ingredients. (a) Self-rising flour, self-rising white flour, self-rising wheat flour, is an intimate mixture of flour, sodium bicarbonate, and the acid reacting substance monocalcium phosphate or sodium acid pyrophosphate or both. It is seasoned with salt. When it is tested by the method prescribed in subsection (c) not less than 0.5 percent of carbon dioxide is evolved. The acid reacting substance is added in sufficient quantity to neutralize the sodium bicarbonate. The combined weight of such acid reacting substance and sodium bicarbonate is not more than 4.5 parts to each 100 parts of flour used. Subject to the conditions and restrictions prescribed by § 15.000 (a), the bleaching ingredients specified in such section may be added as optional ingredients. If the flour used in making the self-rising flour is bleached, the optional bleaching ingredient used therein (see § 15.000 (a)) is also an optional ingredient of the self-rising flour.

(b) When any optional bleaching ingredient is used, the label shall bear the word "Bleached". Wherever the name of the food appears on the label so conspicuously as to be easily seen under customary conditions of purchase, the

word "Bleached" shall immediately and conspicuously precede or follow such name, without intervening written, printed, or graphic matter; except that where such name is a part of a trade-mark or brand, other written, printed, or graphic matter, which is also part of such trade-mark or brand, may so intervene if the word "Bleached" is in such juxtaposition with such trade-mark or brand as to be conspicuously related to such name.

(c) The method referred to in subsection (a) is the method prescribed in "Official and Tentative Methods of Analysis of the Association of Official Agricultural Chemists," 5th edition, 1940, beginning on page 186 under "Gasometric Method with Chittick's Apparatus—Official," except that the following procedure is substituted for the procedure specified therein under "6—Determination":

Weigh 17 grams of the official sample into flask A, add 15-20 glass beads (4-6 mm. diameter) and connect this flask with the apparatus (fig. 22). Open stopcock C and by means of the leveling bulb E bring the displacement solution to the 25 cc. graduation above the zero mark. (This 25 cc. is a partial allowance for the volume of acid to be used in the decomposition). Allow the apparatus to stand 1-2 minutes to insure that the temperature and pressure within the apparatus are the same as those of the room. Close the stopcock, lower the leveling bulb somewhat to reduce the pressure within the apparatus, and slowly run into the decomposition flask from burette F 45 cc. of sulphuric acid (1+5). To prevent the liberated carbon dioxide from escaping through the acid burette into the air, keep the displacement solution in the leveling bulb at all times during the decomposition at a lower level than that in the gas-measuring tube. Rotate and then vigorously agitate the decomposition flask for three minutes to mix the contents intimately. Allow to stand for ten minutes to bring to equilibrium. Equalize the pressure in the measuring tube by means of the leveling bulb and read the volume of gas from the zero point on the tube. Deduct 20 cc. from this reading (this 20 cc. together with previous allowance of 25 cc. compensates for the 45 cc. acid used in the decomposition). Observe the temperature of the air surrounding the apparatus and also the barometric pressure, and multiply the number of cc. of gas evolved by the factor given in table 24—Chapter XLIII for the temperature and pressure observed. Divide the corrected

reading by 100 to obtain the apparent percent by weight of carbon dioxide in the official sample.

Correct the apparent percent of carbon dioxide to compensate for varying atmospheric conditions by immediately assaying a synthetic sample by the same method in the same apparatus.

Prepare the synthetic sample with 16.2 grams of flour, 0.30 gram of monocalcium phosphate, 0.30 gram of salt, and a sufficient quantity of sodium bicarbonate U. S. P. (dried over sulphuric acid) to yield the amount of carbon dioxide recovered in assay of official sample. Determine this quantity by multiplying weight of carbon dioxide recovered in assay of official sample by 1.91.

Divide the weight of carbon dioxide recovered from synthetic sample by weight of carbon dioxide contained in sodium bicarbonate used.

Divide the quotient into the apparent percent of carbon dioxide in official sample to obtain percent carbon dioxide evolved from the official sample.

§15.060 Enriched self-rising flour — Identity; Label statement of optional ingredients. Enriched self-rising flour conforms to the definition and standard of identity, and is subject to the requirements for label statement of optional ingredients, prescribed for self-rising flour by § 15.050, except that—

(1) it contains in each pound not less than 1.66 milligrams and not more than 2.5 milligrams of vitamin B_1, not less than 1.2 milligrams and not more than 1.8 milligrams of riboflavin, not less than 6 milligrams and not more than 9 milligrams of nicotinic acid or nicotinic acid amide, not less than 6 milligrams and not more than 24 milligrams of iron (Fe);

(2) vitamin D may be added in such quantity that each pound of the finished enriched self-rising flour contains not less than 250 U. S. P. units and not more than 1,000 U. S. P. units of vitamin D;

(3) calcium may be added in such quantity that each pound of the finished enriched self-rising flour contains not less than 500 milligrams and not more than 2,000 milligrams of calcium (Ca);

(4) it may contain not more than 5 percent by weight of wheat germ or partly defatted wheat germ; and

(5) when calcium is added as dicalcium phosphate, such dicalcium phosphate is also considered to be an acid-reacting substance.

Iron may be added only in a form which is harmless and assimilable; calcium only in the form of monocalcium phosphate, dicalcium phosphate, tricalcium phosphate, or any mixture of two or more of these. The substances referred to in clauses (1) and (2) may be added in a harmless carrier which does not impair the enriched self-rising flour; such carrier is used only in the quantity necessary to effect an intimate and uniform admixture of such substances with the flour.

§ 15.070 Phosphated flour, phosphated white flour, phosphated wheat flour—Identity; Label statement of optional ingredients. Phosphated flour, phosphated white flour, phosphated wheat flour, conforms to the definition, and standard of identity, and is subject to the requirements for label declaration of optional ingredients, prescribed for flour by § 15.000, except that—

(1) monocalcium phosphate is added in a quantity not less than 0.25 percent and not more than 0.75 percent of the finished phosphated flour; and

(2) in determining whether the ash content complies with the requirements of this regulation allowance is made for the added monocalcium phosphate.

§ 15.080 Whole wheat flour, graham flour, entire wheat flour—Identity: Label statement of optional ingredients. (a) Whole wheat flour, graham flour, entire wheat flour, is the food prepared by so grinding cleaned wheat other than durum wheat and red durum wheat that, when tested by the method prescribed in subsection (c) (2), not less than 90 percent passes through a No. 8 sieve and not less than 50 percent passes through a No. 20 sieve. The proportions of the natural constituents of such wheat, other than moisture, remain unaltered. To compensate for any natural deficiency of enzymes, malted wheat, malted wheat flour, malted barley flour, or any combination of two or more of these, may be used in a quantity, not more than 0.5 percent. The moisture content of whole wheat flour is not more than 15 per cent. Unless such addition conceals damage or inferiority of the whole wheat flour or makes it appear better or of greater value than it is, the optional bleaching ingredient nitrogen trichloride, chlorine, or a mixture of nitrosyl chloride and chlorine may be added in a quantity not more than sufficient for bleaching and artificial aging effects.

(b) When any optional bleaching ingredient is used, the label shall bear the word "Bleached." Wherever the name

of the food appears on the label so conspicuously as to be easily seen under customary conditions of purchase, such word shall immediately and conspicuously precede or follow such name without intervening written, printed or graphic matter; except that where such name is a part of a trade-mark or brand, other written, printed, or graphic matter, which is also a part of such trade-mark or brand, may so intervene if the word "Bleached" is in such juxtaposition with such trade-mark or brand as to be conspicuously related to such name.

(c) For the purpose of this section—

(1) Moisture is determined by the method prescribed in "Official and Tentative Methods of Analysis of the Association of Official Agricultural Chemists," 5th edition, 1940, page 211, under "Vacuum Oven Method—Official."

(2) The method referred to in subsection (a) is as follows: Use No. 8 and No. 20 sieves, having standard 8 inch full height frames, complying with the specifications for wire cloth and sieve frames in "Standard Specifications for Sieves" published March 1, 1940, in L. C. 584 of the U. S. Department of Commerce, National Bureau of Standards. Fit a No. 8 sieve into a No. 20 sieve. Attach bottom pan to the No. 20 sieve. Pour 100 grams of the sample into the No. 8 sieve. Attach cover and hold the assembly in a slightly inclined position with one hand. Shake the sieves by striking the sides against the other hand with an upward stroke, at the rate of about 150 times per minute. Turn the sieves about one-sixth of a revolution, each time in the same direction, after each 25 strokes. Continue shaking for two minutes. Weigh the material which fails to pass through the No. 8 sieve and the material which passes through the No. 20 sieve.

§ 15.090 Bromated whole wheat flour, bromated graham flour, bromated entire wheat flour—Identity: Label statement of optional ingredients. Bromated whole wheat flour, bromated graham flour, bromated entire wheat flour, conforms to the definition and standard of identity, and is subject to the requirements for label statement for optional ingredients, prescribed for whole wheat flour by § 15.080, except that potassium bromate is added in a quantity not exceeding 75 parts to each million parts of finished bromated whole wheat flour.

§ 15.100 Whole durum wheat flour—Identity: Label statement of optional ingredients. Whole durum wheat flour conforms to the definition and standard of identity, and is

subject to the requirements for label statement of optional ingredients, prescribed for whole wheat flour by § 15.080, except that cleaned durum wheat, instead of cleaned wheat other than durum wheat and red durum wheat, is used in its preparation.

§ 15.110 Crushed wheat, coarse ground wheat—Identity. Crushed wheat, coarse ground wheat, is the food prepared by so crushing cleaned wheat other than durum wheat and red durum wheat that, when tested by the method prescribed in § 15.080 (c) (2), 40 per cent or more passes through a No. 8 sieve and less than 50 percent passes through a No. 20 sieve. The proportions of the natural constituents of such wheat, other than moisture, remain unaltered. Crushed wheat contains not more than 15 percent of moisture as determined by the method prescribed in "Official and Tentative Methods of Analysis of the Association of Official Agricultural Chemists," 5th edition, 1940, page 353, under "Preparation of Sample—Official" and "Moisture I. Drying with Heat—Official."

§ 15.120 Cracked Wheat—Identity. Cracked wheat is the food prepared by so cracking or cutting into angular fragments cleaned wheat other than durum wheat and red durum wheat that, when tested by the method prescribed in § 15.080 (c) (2), not less than 90 percent passes through a No. 8 sieve and not more than 20 percent passes through a No. 20 sieve. The proportions of the natural constituents of such wheat, other than moisture, remain unaltered. Cracked wheat contains not more than 15 percent of moisture as determined by the method prescribed in "Official and Tentative Methods of Analysis of the Association of Official Agricultural Chemists," 5th edition, 1940, page 353, under "Preparation of Sample—Official" and "Moisture I. Drying with Heat—Official."

§ 15.130 Farina—Identity. (a) Farina is the food prepared by grinding and bolting cleaned wheat, other than durum wheat and red durum wheat, to such fineness that, when tested by the method prescribed in subsection (b) (2), it passes through a No. 20 sieve, but not more than 3 percent passes through a No. 100 sieve. It is freed from bran coat, or bran coat and germ, to such extent that the percent of ash therein, calculated to a moisture-free basis, is not more than 0.6 percent. Its moisture content is not more than 15 percent.

(b) For the purposes of this section—

(1) Ash and moisture are determined by the methods therefor referred to in § 15.000 (c).

(2) The method referred to in subsection (a) is as follows; Use No. 20 and No. 100 sieves, having standard 8 inch full height frames, complying with the specifications for wire cloth and sieve frames in "Standard Specifications for Sieves," published March 1, 1940, in L. C. 584 of the U. S. Department of Commerce, National Bureau of Standards. Fit a No. 20 sieve into a No. 100 sieve. Attach bottom pan to the No. 100 sieve. Pour 100 grams of the sample into the No. 20 sieve. Attach cover and hold the assembly into a slightly inclined position with one hand. Shake the sieves by striking the sides against the other hand with an upward stroke, at the rate of about 150 times per minute. Turn the sieves about one-sixth of a revolution, each time in the same direction, after each 25 strokes. Continue shaking for two minutes. Weigh the material which fails to pass through the No. 20 sieve and the material which passes through the No. 100 sieve.

§ 15.140 Enriched farina—Identity; Label statement of optional ingredients. (a) Enriched farina conforms to the definition and standard of identity prescribed for farina by § 15.130, except that—

(1) it contains in each pound not less than 1.66 milligrams of vitamin B_1, not less than 1.2 milligrams of riboflavin, not less than 6 milligrams of nicotinic acid or nicotinic acid amide, and not less than 6 milligrams of iron (Fe);

(2) vitamin D may be added in such quantity that each pound of the finished enriched farina contains not less than 250 U. S. P. units of optional ingredient vitamin D;

(3) calcium may be added in such quantity that each pound of the finished enriched farina contains not less than 300 milligrams of the optional ingredient calcium (Ca);

(4) it may contain not more than 6 percent by weight of the optional ingredient wheat germ or partly defatted wheat germ;

(5) it may contain not less than 0.5 percent and not more than 1 percent by weight of the optional ingredient di-sodium phosphate; and

(6) in determining whether the ash content complies with the requirements of this regulation allowance is made for any added minerals.

Iron may be added only in a form which is harmless and assimilable; calcium only in the form of monocalcium phosphate, dicalcium phosphate, tricalcium phosphate, or any mixture of two or more of these; vitamin D only as ir-

radiated yeast or as a concentrate of vitamin D in a food oil. The substances referred to in clauses (1) and (2) may be added in a harmless carrier which does not impair the enriched farina; such carrier is used only in the quantity necessary to effect an intimate and uniform admixture of such substances with the farina.

(b) When the optional ingredient disodium phosphate is used, the label shall bear the statement "Disodium Phosphate Added for Quick-cooking." Wherever the name of the food appears on the label so conspicuously as to be easily seen under customary conditions of purchase, such statement shall immediately and conspicuously precede or follow such name, without intervening written, printed, or graphic matter; except that where such name is a part of a trade-mark or brand, other written, printed, or graphic matter, which is also a part of such trade-mark or brand, may so intervene, if such statement is in such juxtaposition with such trade-mark or brand as to be conspicuously related to such name.

§ 15.150 Semolina—Identity. (a) Semolina is the food prepared by grinding and bolting cleaned durum wheat to such fineness that, when tested by the method prescribed in § 15.130 (b) (2), it passes through a No. 20 sieve, but not more than 3 percent passes through a No. 100 sieve. It is freed from bran coat, or bran coat and germ, to such extent that the percent of ash therein, calculated to the moisture-free basis, is not more than 0.9 percent. Its moisture content is not more than 15 percent.

(b) For the purposes of this section—

Ash and moisture are determined by the methods therefor referred to in § 15.000 (e).

Any interested person may, within 20 days from the date of the publication of this proposed order in the Federal Register, file exceptions thereto with the Hearing Clerk of the Federal Security Agency, Office of the Assistant General Counsel, Room 2240, South Building, 14th Street and Independence Avenue, Washington, D. C. Exceptions shall point out with particularity the alleged errors in the proposed order, and shall contain specific references to the pages of the transcript of the testimony or to the exhibits on which each exception is based. Such exceptions may be accompanied by a memorandum brief in support thereof.

March 28, 1941.

Wayne Coy,

(Seal) *Acting Federal Security Administrator.*

(F. R. Doc. 41-2329; Filed, March 29, 1941; 11:27 a. m.)

FEDERAL SECURITY AGENCY.

Food and Drug Administration.

[Docket No. F. D. C.-21]

In the Matter of a Definition and Standard of Identity for Each of the Following Foods: * * * (N) Enriched Farina * * *

Correction

In § 15.140 (a) (3) appearing at page 1737 in the Federal Register for Tuesday, April 1, 1941, the figure 300 should read 500. In subparagraph (4) of the same section the figure 6 should read 8.

April 18, 1941.

BEFORE THE ADMINISTRATOR

Federal Security Agency.

In the Matter of a Definition and Standard of Identity for Each of the Following Foods: (A) Flour, White Flour, Wheat Flour, Plain Flour; (B) Durum Flour; (C) Whole Wheat Flour, Graham Flour, Entire Wheat Flour; (D) Cracked Wheat; (E) Crushed Wheat; (F) Whole Durum Wheat Flour; (G) Self-Rising Flour, Self-Rising White Flour, Self-Rising Wheat Flour; (H) Phosphated Flour, Phosphated Wheat Flour; (I) Farina; and (J) Semolina.	Docket No. FDC-21

EXCEPTIONS OF THE QUAKER OATS COMPANY TO THE PROPOSED ORDER, PROPOSED FINDINGS OF FACT, AND PROPOSED REGULATIONS AS PUBLISHED IN THE FEDERAL REGISTER FOR APRIL 1, 1941, AT PAGES 1729 THROUGH 1737.

BEFORE THE ADMINISTRATOR

Federal Security Agency.

In the Matter of a Definition and Standard of Identity for Each of the Following Foods: (A) Flour, White Flour, Wheat Flour, Plain Flour; (B) Durum Flour; (C) Whole Wheat Flour, Graham Flour, Entire Wheat Flour; (D) Cracked Wheat; (E) Crushed Wheat; (F) Whole Durum Wheat Flour; (G) Self-Rising Flour, Self-Rising White Flour, Self-Rising Wheat Flour; (H) Phosphated Flour, Phosphated Wheat Flour; (I) Farina; and (J) Semolina.	Docket No. FDC-21

EXCEPTIONS OF THE QUAKER OATS COMPANY TO THE PROPOSED ORDER, PROPOSED FINDINGS OF FACT, AND PROPOSED REGULATIONS AS PUBLISHED IN THE FEDERAL REGISTER FOR APRIL 1, 1941, AT PAGES 1729 THROUGH 1737.

The Quaker Oats Company, a corporation organized and existing under the laws of the State of New Jersey, with offices at Chicago, Illinois, hereby respectfully takes exception to the proposed Order, proposed Findings of Fact, and proposed Regulations in the above entitled matter as published in the Federal Register for April 1, 1941, at Pages 1729 through 1737, as follows:

I To proposed Finding of Fact No. 83, which reads:

"In general, the interest of consumers is affected by the enrichment of farina with vitamins and minerals in the same way as has been outlined in connection with the enrichment of flour in findings 33 to 34, inclusive."

II To proposed Finding of Fact No. 86, which reads:

"Farina enriched with vitamins and minerals has not acquired a common or usual name; an accurate designation for the product is 'Enriched farina'."

III To Section 15.140 of the proposed Regulations captioned "Enriched Farina—Identity; Label Statement of Optional Ingredients," which reads:

"(a) Enriched farina conforms to the definition and

standard of identity prescribed for farina by Section 15.130, except that—

(1) it contains in each pound not less than 1.66 milligrams of vitamin B_1, not less than 1.2 milligrams of riboflavin, not less than 6 milligrams of nicotinic acid or nicotinic acid amide, and not less than 6 milligrams of iron (Fe);

(2) vitamin D may be added in such quantity that each pound of the finished enriched farina contains not less than 250 U. S. P. units of the optional ingredient vitamin D;

(3) calcium may be added in such quantity that each pound of the finished enriched farina contains not less than 300 milligrams of the optional ingredient calcium (Ca);

(4) it may contain not more than 6 per cent by weight of the optional ingredient wheat germ or partly defatted wheat germ;

(5) it may contain not less than 0.5 per cent and not more than 1 per cent by weight of the optional ingredient disodium phosphate; and

(6) in determining whether the ash content complies with the requirements of this regulation allowance is made for any added minerals.

Iron may be added only in a form which is harmless and assimilable; calcium only in the form of monocalcium phosphate, dicalcium phosphate, tricalcium phosphate, or any mixture of two or more of these; vitamin D only as irradiated yeast or as a concentrate of vitamin D in a food oil. The substances referred to in clauses (1) and (2) may be added in a harmless carrier which does not impair the enriched farina; such carrier is used only in the quantity necessary to effect an intimate and uniform admixture of such substances with the farina.

"(b) When the optional ingredient disodium phosphate is used, the label shall bear the statement 'Disodium Phosphate Added for Quick Cooking.' Wherever the name of the food appears on the label so conspicuously as to be easily seen under customary conditions of purchase, such statement shall immediately and conspicuously precede or follow such name, without intervening written, printed, or graphic matter; except that where such name is a part of a trade mark of brand, other written, printed, or graphic matter, which is also a part of such trade mark or brand, may so intervene, if such statement is in such juxtaposition with such trade mark or brand as to be conspicuously related to such name."

As grounds for its exceptions, The Quaker Oats Company states:

A. Contrary to the provisions of Section 701(e) of the Federal Food, Drug & Cosmetics Act, the Administrator gave no notice of a hearing to establish a reasonable definition and standard of identity for "Enriched Farina." The notice of the Administrator as published in the Federal Register for August 3, 1940, at Pages 2746 through 2749, is entitled and gives notice of public hearings for the purpose of receiving evidence upon the basis of which regulations may be promulgated, fixing and establishing a reasonable definition and standard of identity for certain foods, as follows:

"Notice of Public Hearings for Purpose of Receiving Evidence Upon Basis of Which Regulations May Be Promulgated Fixing and Establishing a Definition and Standard of Identity for Each of the Following Foods: (A) Flour, White Flour, Wheat Flour, Plain Flour; (B) Durum Flour; (C) Whole Wheat Flour, Graham Flour, Entire Wheat Flour; (D) Cracked Wheat; (E) Crushed Wheat; (F) Whole Durum Wheat Flour; (G) Self-Rising Flour, Self-Rising White Flour, Self-Rising Wheat Flour; (H) Phosphated Flour, Phosphated White Flour, Phosphated Wheat Flour; (I) Farina; and (J) Semolina." The proposed Order, proposed Findings of Fact, and proposed Regulations of the Administrator as published in the Federal Register of April 1, 1941, at Pages 1729 through 1737, is entitled:

"In the Matter of a Definition and Standard of Identity for Each of the Following Foods: (A) Flour, White Flour, Wheat Flour, Plain Flour; (B) Enriched Flour; (C) Bromated Flour; (D) Enriched Bromated Flour; (E) Durum Flour; (F) Self-Rising Flour, Self-Rising White Flour, Self-Rising Wheat Flour; (G) Enriched Self-Rising Flour; (H) Whole Wheat Flour, Graham Flour, Entire Wheat Flour; (I) Bromated Whole Wheat Flour; (J) Whole Durum Wheat Flour; (K) Crushed Wheat, Coarse Ground Wheat; (L) Cracked Wheat; (M) Farina; (N) Enriched Farina; (O) Semolina."

It is obvious from the change in the title that a matter not covered by the notice of the public hearings and upon which no notice was given, has been acted upon by the Administrator. The evidence introduced by the Administrator (Testimony of Joseph Callaway, Jr., Record, Pages 1001 to 1014, and Dr. Virdell E. Munsey, Record, Pages 1014 to

1021) pursuant to said notice, covers only farina. Evidence offered by The Quaker Oats Company, (Record, Pages 1021 to 1036A), by Cream of Wheat Corporation (Record, Pages 1417 to 1519) and by others, pursuant to said Notice, relates only to farina alone and farina with optional ingredients. Neither the Administrator nor farina manufacturers introduced any evidence on a food to be known as "Enriched Farina," which in addition to farina would contain certain other required ingredients.

Due to the absence of notice on a matter of vital concern to The Quaker Oats Company, it was not even represented by counsel at said hearings, but relied upon said Notice to cover farina alone and farina with such optional ingredients as should be justified by the evidence. Had The Quaker Oats Company been notified of public hearings for the purpose of promulgating regulations fixing and establishing a reasonable definition and standard of identity for a product to be called "Enriched Farina," it would have presented its views at length and would have been represented by counsel.

B. The Notice and the Record are entirely devoid of any reference to a product designated as "Enriched Farina," and no evidence was introduced by the Administrator or by manufacturers respecting required ingredients for "Enriched Farina." (See Record citations above.) Finding of Fact No. 83, quoted above, is entirely unsupported by any evidence in the Record, and the Record citations published with said Finding of Fact do not afford any basis for said Finding. Had The Quaker Oats Company been given notice of public hearings with respect to "Enriched Farina," it could have introduced evidence contrary to said unsupported Finding of Fact No. 83. Indeed, said Finding of Fact No. 83 is contradicted by Findings of Fact Nos. 81 and 84, (Pages 1733 and 1734, Federal Register, April 1, 1941) which read:

"81. Farina is used as a breakfast food and as an ingredient of macaroni products. It is not as widely consumed as flour, but it is extensively used as a cereal food for children and in many cases is the only cereal food used during a period of their growth.

84. Because of the small quantities in which farina is ordinarily consumed, and because of its special use in diets of some children there is occasion for the enrichment of farina with quantities of vitamins and minerals substantially in excess of the reasonable maxima for flour. Find-

ings 44 and 45 are applicable to farina, except that farina is not used for making bread and a reasonable limit for the wheat germ is 8 per cent."

Finding of Fact 86, quoted above, is wholly unsupported by any evidence of record, and the Record citations published with said Finding of Fact do not afford any basis for said Finding. In fact, said Finding of Fact is controverted by the Record (Record, Page 1023) wherein Dr. Gunderson testified:

"The food product to which I refer is known country wide to the public by the clear front panel package labelled as 'Quaker Farina Wheat Cereal Enriched with Vitamin D'."

Dr. Gunderson (Record, Page 1025) by his statement "If one is adopted, I suggest that provision be made to permit reasonable mineral enrichment with optional nutritional ingredients;" Dr. Robert S. Harris (Record, Page 1439) wherein he stated "I request that the following ingredients be allowed as optional ingredients of farina * * *;" and the testimony of other witnesses appearing elsewhere in the Record clearly show that they were not talking about a new and unknown product to be designated as "Enriched Farina," but simply about farina with certain optional ingredients.

C. Section 15.140 "Enriched Farina—Identity; Label Statement of Optional Ingredients," quoted above, does not set forth "a reasonable definition and standard of identity" or "a reasonable standard of quality," as required by Section 401 of the Federal Food, Drug & Cosmetics Act. Under Section 401, the Administrator has the power to establish for a product "a reasonable definition and standard of identity," and he has the power to "designate the optional ingredients which shall be named on the label." He does not have the power to create unknown foods or classes of foods. It is the Administrator's duty under the statute to establish reasonable definitions and standards of identity and to allow optional ingredients when justified by the evidence. On the basis of the Notice and the Statute, The Quaker Oats Company and the other manufacturers of farina were justified in assuming that only a definition and standard of identity for farina alone and with optional ingredients would be considered. The evidence in the Record is clear and convicing that Vitamin D should be allowed as an optional ingredient in farina. There is also evidence that certain other vitamins and

minerals should be permitted as optional ingredients. There is no evidence that some of these vitamins and minerals other than Vitamin D should be required in order that farina may be enriched with Vitamin D.

D. The Quaker Oats Company since 1932 (Record, Page 1023) has sold a product known as "Quaker Farina Wheat Cereal Enriched with Vitamin D." Without statutory authority, and supported by no evidence of record, the Administrator proposes to destroy the long established business of The Quaker Oats Company in Farina enriched with Vitamin D. If Section 15.140 of the proposed Regulations is adopted, The Quaker Oats Company may add Vitamin D to its farina only upon the condition that it add four other ingredients to it, namely Vitamin B_1, riboflavin, nicotinic acid, and iron, in order to continue the manufacture and sale of farina enriched with Vitamin D. There is no evidence in the Record as to why, with respect to farina, Vitamin B_1, riboflavin, nicotinic acid and iron should be required as a condition to the fortification of farina with Vitamin D. That an anology cannot be drawn to flour is clear from the Administrator's Fiding of Fact No. 84, from the evidence of the Administrator's witnesses, Joseph Calaway, Jr., (Record, Page 1003 and Page 1013) and Dr. Munsey (Record, Page 1014). Not only does the Record disclose that farina is not flour, but also that its uses are different.

There is no more reason for making nicotinic acid, iron, riboflavin, or Vitamin B_1 required ingredients for a product designated by the Administrator as "Enriched Farina" than there is for making Vitamin D a required ingredient. Certainly the Record contains no such reason. Had The Quaker Oats Company and other manufacturers of farina been given a notice, evidence could have been introduced showing that farina is widely consumed by infants and children and almost always in combination with milk, from which they obtain much of their needed calcium; that Vitamin D is essential to the assimilation of calcium; that other sources than farina, including milk, in a properly regulated diet will furnish Vitamin B_1, nicotinic acid, riboflavin and iron; that little is known about nicotinic acid in cereals, that it is difficult to measure; that riboflavin is not readily available for fortification uses; that cereals are not rich sources of nicotinc acid or riboflavin; that it is very difficult to add iron to farina.

It is, therefore, respectfully submitted that Findings of Fact Nos. 83 and 86 are erroneous and not supported by any evidence of record, and that Finding of Fact No. 86 concerns an unknown product not covered in said Notice of Public Hearings. These Findings of Fact should, therefore, be omitted. It is further respectfully submitted, for the reasons stated above, that Section 15.140 of the proposed Regulations entitled "Enriched Farina—Identity; Label Statement of Optional Ingredients" is erroneous, not supported by evidence of record, and concerns an unknown product not covered by said Notice of Public Hearings. Said Section 15.140 should, therefore, be revised to eliminate any reference to a product designated as "Enriched Farina," should eliminate any required ingredients, and should provide only for optional ingredients in farina.

The Quaker Oats Company,
By R. Douglas Stewart,
First Vice President.

William D. McKenzie,
William D. McKenzie,
James M. Best,
James M. Best,
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BEFORE THE ADMINISTRATOR FEDERAL SECURITY AGENCY.

In the Matter of a Definition and Standard of Identity for each of the Following Foods: (A) Flour, White Flour, Wheat Flour, Plain Flour; (B) Enriched Flour; (C) Bromated Flour; (D) Enriched Bromated Flour; (E) Durum Flour; (F) Self-Rising Flour, Self-Rising White Flour, Self-Rising Wheat Flour; (G) Enriched Self-Rising Flour; (H) Whole Wheat Flour, Graham Flour, Entire Wheat Flour; (I) Bromated Whole Wheat Flour; (J) Whole Durum Wheat Flour; (K) Crushed Wheat, Coarse Ground Wheat; (L) Cracked Wheat; (M) Farina; (N) Enriched Farina; (O) Semolina.	Docket No. FDC-21.

EXCEPTIONS OF WISCONSIN ALUMNI RESEARCH FOUNDATION TO PROPOSED ORDER AND MEMORANDUM BRIEF IN SUPPORT THEREOF.

10. In the failure of the Administrator to include in the Proposed Order a provision permitting the use of Vitamin D as an optional ingredient in the product farina, as defined in Section 15.130 Farina-identity of the Proposed Order (R. 396-7; 416; 754-6; 1706; 1724).

11. In the requirement of the Proposed Order of the addition of certain prescribed amounts of Vitamin B_1, riboflavin, nicotinic acid or nicotinic acid amide and iron to the product enriched farina, as defined in Section 15.140 Enriched farina-identity: Label statement of optional ingredients of the Proposed Order (R. 396-7; 416; 754-6; 1706; 1724).

12. In the failure of the Administrator to include in the Proposed Order separate definitions and standards of identity for flour, bromated flour, self-rising flour, phosphated flour, whole wheat flour, crushed wheat and farina in which Vitamin D is permitted as an optional ingredient in such products (R. 396-7; 416; 754-6; 1706; 1724).

BEFORE THE FEDERAL SECURITY AGENCY.

Food and Drug Administration.

In the Matter of a Definition and Standard of Identity for Each of the Following Foods: (A) Flour, White Flour, Wheat Flour, Plain Flour; (B) Enriched Flour; (C) Bromated Flour; (D) Enriched Bromated Flour; (E) Durum Flour; (F) Self-Rising Flour, Self-Rising White Flour, Self-Rising Wheat Flour; (G) Enriched Self-Rising Flour; (H) Whole Wheat Flour, Graham Flour, Entire Wheat Flour; (I) Bromated Whole Wheat Flour; (J) Whole Durum Wheat Flour; (K) Crushed Wheat, Coarse Ground Wheat; (L) Cracked Wheat; (M) Farina; (N) Enriched Farina; (O) Semolina.	(Docket No. F. D. C.-21)

EXCEPTIONS OF MILLERS' NATIONAL FEDERATION TO THE PROPOSED ORDER, PROPOSED FINDINGS OF FACT AND PROPOSED REGULATIONS, AND BRIEF IN SUPPORT THEREOF.

Exception 2.

Farina is used largely as a breakfast food and as an ingredient of macaroni products. (Millers' National Federation printed brief of December 12, 1940, page 42; Administrator's Proposed Findings of Fact 81, Federal Register April 1, 1941, page 1733.) In our printed brief of December 12, 1940 we pointed out that the processors and distributors of Farina as a breakfast food have different ideas and practices with respect to the vitamins and/or minerals to be added to their products, and we recommended that the Administration in its determination as to what vitamins and minerals should be required or

permitted as optional ingredients should adopt the recommendations of the processors and distributors of Farina.

In view of the apparent diversity of opinions among processors and distributors of Farina as to what nutritive ingredients should be added to Farina, it is our suggestion that a separate definition and standard of identity of Farina should be promulgated permitting the inclusion in this special type of Farina of any one or more, or combination of, the following nutritive ingredients: Thiamin (B_1); Riboflavin (B_2); Nicotinic Acid; Vitamin D; Calcium; Iron and Phosphorus.

2. A separate definition and standard of identity for a special type of Farina to which may be added any one or more of the following nutrient ingredients, or a combination of them: Thiamin (B_1); Riboflavin (B_2); Nicotinic Acid; Vitamin D; Calcium; Iron and Phosphorus. A separate definition and standard of identity of this type of Farina is necessary in our opinion in order to allow processors and distributors of Farina to market special types of Farina. For example, as pointed out in our brief of December 12, 1940, the Quaker Oats Company has been adding Vitamin D to Farina since April 1932 (R. 1023), and under our interpretation of the Administrator's exclusive appropriation principle with respect to the definitions and standards, the Quaker Oats Company would be prevented in the future from marketing its Farina containing Vitamin D because it would not conform to the definition and standard of identity of Farina, Section 15.130, nor to the definition and standard of identity of Enriched Farina, Section 15.140.

In our opinion the principles enunciated under Findings of Fact 36 and 37 (Federal Register April 1, 1941, page 1731) should have no application to breakfast foods.

As previously stated, we are informed that several, at least, of the principal processors and distributors of Farina will file separate exception briefs fully stating their exceptions to the proposed regulations.

BEFORE THE FEDERAL SECURITY AGENCY.

Food and Drug Administration.

In the Matter of a Definition and Standard of Identity for each of the following foods: (A) Flour, White Flour, Wheat Flour, Plain Flour; (B) Enriched Flour; (C) Bromated Flour; (D) Enriched Bromated Flour; (E) Durum Flour; (F) Self-Rising Flour; Self-Rising White Flour; Self-Rising Wheat Flour; (G) Enriched Self-Rising Flour; (H) Whole Wheat Flour, Graham Flour; Entire Wheat Flour; (I) Bromated Whole Wheat Flour; (J) Whole Durum Wheat Flour; (K) Crushed Wheat, Coarse Ground Wheat; (L) Cracked Wheat; (M) Farina; (N) Enriched Farina; (O) Semolina.	(Docket No. F. D. C.-21.)

EXCEPTIONS OF PILLSBURY FLOUR MILLS COMPANY TO THE PROPOSED ORDER, PROPOSED FINDINGS OF FACT AND PROPOSED REGULATIONS, AND BRIEF IN SUPPORT THEREOF.

Exception 2.

That the Administrator has erred in failing to promulgate a separate definition and standard of identity for a food consisting of farina to which may be added any one or more of the following nutrient ingredients, or a combination of them: Thiamin (B_1); Riboflavin (B_2); Nicotinic Acid; Vitamin D; Calcium; Iron and Phosphorus, as optional ingredients. Such food to be named "Farina" followed by the name of any such optional ingredient added. This exception is on the grounds set forth in the exceptions and brief of Millers' National Federation filed in this matter.

General Exceptions.

Exception 2 thereunder.

Evidence was introduced at the hearings with respect to plain farina and farina with added optional ingredients. Pillsbury Flour Mills Company for some time last past has manufactured and sold extensively to the public farina to which only Vitamin B_1 has been added. Other companies have manufactured and sold to the public a farina with other vitamins separately or a combination of vitamin and other nutrient ingredients added, and we submit that Pillsbury Flour Mills Company and such other companies should be permitted to continue to manufacture and sell, under a separate definition and standard of identity, farina to which one or more of the aforesaid nutrient ingredients or a combination thereof have been added as optional ingredients. This, as we understand it, is in accordance with the testimony and recommendations of witnesses who testified at the hearings held with respect to this matter.

Respectfully submitted,
Pillsbury Flour Mills Company
By Clark Hempstead,
And Bradshaw Mintener,
Its Attorneys.

Dated April 19, 1941.
Clark Hempstead,
Bradshaw Mintener,
Attorneys.
301 Metropolitan Life Building,
Minneapolis, Minnesota.

Entered May 26, 1941.

TITLE 21—FOOD AND DRUGS.

Chapter I—Food and Drug Administration

[Docket No. FDC-21]

Part 15—Wheat Flour and Related Products; Definitions and Standards of Identity.

In the Matter of a Definition and Standard of Identity for Each of the Following Foods: (A) Flour, White Flour, Wheat Flour, Plain Flour; (B) Enriched Flour; (C) Bromated Flour; (D) Enriched Bromated Flour; (E) Durum Flour; (F) Self-Rising Flour, Self-Rising White Flour, Self-Rising Wheat Flour; (G) Enriched Self-Rising Flour; (H) Phosphated Flour, Phosphated White Flour, Phosphated Wheat Flour; (I) Whole Wheat Flour, Graham Flour, Entire Wheat Flour; (J) Bromated Whole Wheat Flour; (K) Whole Durum Wheat Flour; (L) Crushed Wheat, Coarse Ground Wheat; (M) Cracked Wheat; (N) Farina; (O) Enriched Farina; (P) Semolina.

Final Order.

By virtue of authority vested in me by the provisions of the Federal Food, Drug, and Cosmetic Act, 52 Stat. 1046, 21 U.S.C. sec. 341 (Supp. V, 1939); the Reorganization Act of 1939, 53 Stat. 561 ff., 5 U.S.C. sec. 133-133r (Supp. V, 1939); Reorganization Plans Nos. I (53 Stat. 1423, 4 F.R. 2727) and No. IV (5 F.R. 2421); upon the basis of evidence received at the hearings herein; and upon consideration of the exceptions filed against the proposed order issued by the Acting Federal Security Administrator on March 28, 1941 (6 F.R. 1729-1937), the following order is promulgated hereby:

Findings of Fact.

1. The food commonly and usually known as "flour", "white flour", "wheat flour", or "plain flour", is manufactured from wheat, both hard and soft, other than durum wheat and red durum wheat.

2. Flour is used primarily for making white bread and

biscuit, and consumers of flour normally expect that it will be suitable for these purposes.

3. In making flour the wheat is first cleaned. It is usually tempered. It is then ground and bolted so as to separate the inner portion of the wheat berry, known as the endosperm, from the outer portions, known as the bran coat, or from both bran coat and germ. Flour consists essentially of finely ground endosperm. In the milling process the separation of bran coat and germ from endosperm is never complete, but a certain degree of separation is necessary to produce flour which will make acceptable white bread and biscuit.

4. Where all the flour milled from the wheat used is combined without separation into grades, the flour is called "straight flour." That portion which is most nearly free of bran coat and germ is frequently taken off and sold as "patent flour." The remaining portion, which contains more bran coat and germ than straight flour, is known as "clear flour."

5. "Straight flours" will make acceptable white bread and biscuit. As the degree of removal of bran coat and germ is lessened, flours become progressively less desirable for such purposes until so much bran coat and germ remain that acceptable white bread and biscuit cannot be made. However, such products are suitable for other food uses and are usually sold under such designations as "low-grade flour" and "second clear flour." Products containing even more bran coat and germ are sold usually as animal feed.

6. A reasonably accurate criterion of the degree of separation of bran coat, or bran coat and germ, from endosperm is the ash content of the flour, since the ash content of the bran coat is some 20 to 25 times that of the endosperm and the ash content of the germ some 10 to 15 times that of the endosperm.

7. In general, a limit on ash content can be used to distinguish between flours which will make acceptable white bread and biscuit and those which will not, but the limit is not the same for high protein flours (hard wheat flours) and low protein flours (soft wheat flours). In high protein flours, particularly those used for breadmaking, a somewhat lesser degree of separation is acceptable than in low protein flours.

8. In most straight flours the percent of ash is not more

than one-twentieth of the percent of protein and is usually somewhat less.

9. Increased amounts of bran coat and germ which increase the percent of ash to a point where it exceeds that of straight flour by more than 0.3 result in products which will not make acceptable white bread or biscuit. Products containing more ash than one-twentieth of the protein plus 0.3 percent are not generally sold in the household trade and are not generally used to make white bread or biscuit.

10. A maximum ash limit to one-twentieth of the protein plus 0.3 percent will distinguish reasonably effectively between flour suitable for making white bread and biscuits and products not suitable for those purposes.

11. Variation in the moisture content of flour after manufacture causes variations in the percent of protein and ash. The effect of such variations can be eliminated by calculating the percent of protein and ash to a moisture-free basis. When such calculation is made the figure 0.35 would be approximate equivalent of, and should be substituted for, the figure 0.3 in Findings 9 and 10.

12. All flour contains some moisture. Excessive moisture, however, impairs the keeping qualities of flour and unnecessarily increases its weight. A reasonable limit for moisture, which is not exceeded in good milling practice, is 15 percent.

13. Flour is a finely ground product and the degree of fineness is a distinguishing characteristic of flour. Such fineness is secured in good milling practice by bolting the flour through a cloth having openings not larger than those of woven wire cloth designated "149 micron (No. 100)" in table I of "Standard Specifications for Sieves", published March 1, 1940, in L. C. 584 of the U. S. Department of Commerce, National Bureau of Standards.

14. Malted wheat is sometimes mixed with wheat used for making flour, or malted wheat flour or malted barley flour is sometimes added to flour, in small amounts so as to compensate for natural deficiencies of enzymes necessary for breadmaking. A reasonable maximum limit for malted barley flour so added is 0.25 percent.

15. A satisfactory and reliable method for the determination of ash content of flour is that prescribed in the book "Official and Tentative Methods of Analysis of the Association of Official Agricultural Chemists", 4th edition, 1935, page 207, under the caption "Method I—Official."

This method has recently been republished in the book "Official and Tentative Methods of Analysis of the Association of Official Agricultural Chemists", 5th edition, 1940, page 212, under the caption "Method I—Official." This method is well-known and widely used when examining flour for its ash content.

16. A satisfactory and reliable method for determination of moisture in flour is that prescribed in the book "Official and Tentative Methods of Analysis of the Association of Official Agricultural Chemists", 4th edition, 1935, page 206, under the caption "Vacuum Oven Method—Official." The same method has recently been republished in the book "Official and Tentative Methods of Analysis of the Association of Official Agricultural Chemists", 5th edition, 1940, page 211, under the caption "Vacuum Oven Method—Official." This method is well-known and widely used when examining flour for its moisture content.

17. The protein content of flour is ordinarily calculated from the nitrogen content of the flour by multiplying the nitrogen content by 5.7. A satisfactory and reliable chemical method for determination of nitrogen is that prescribed in the book "Official and Tentative Methods of Analysis of the Association of Official Agricultural Chemists", 4th edition, 1935, page 25, under the caption "Kjeldahl-Gunning-Arnold Method—Official." The same method has been recently republished in the book "Official and Tentative Methods of Analysis of the Association of Official Agricultural Chemists", 5th edition, 1940, page 26, under the caption "Kjeldahl-Gunning-Arnold Method—Official." This method is well-known and widely used for determining nitrogen in flour.

18. Flour as first prepared is slightly colored by the natural coloring in the wheat. It is a common practice in the milling industry to bleach the flour by treating it with one or more of the following bleaches or bleaching agents:

(1) Oxides of nitrogen.
(2) Chlorine.
(3) Nitrosyl chloride.
(4) Nitrogen trichloride.
(5) Benzoyl peroxide in a carrier consisting of either potassium alum and magnesium carbonate, or a mixture of calcium sulphate and magnesium carbonate, the weight of the carrier being in no case more than six times that of the benzoyl peroxide.

19. Besides the bleaching effect, chlorine, nitrosyl chloride and nitrogen trichloride have an artificial aging effect on the flour so treated. Only enough of the bleaching agent or agents to accomplish such desired effects is used. Excessive quantities impair the flour.

20. Flour so bleached is whiter than freshly milled unbleached flour, but is similar in color to unbleached flour naturally aged. Since about 1920 it has been prevailing trade practice to label flours treated with bleaching agents as "bleached." Many consumers have come to distinguish between bleached and unbleached flour, and are familiar with and understand the word "bleached" as applied to flour. The word "bleached", as so applied, has become the common name of the ingredients added to the flour through the bleaching process.

21. Some flour of high protein content, to which small amounts of potassium bromate have been added, can be made into dough which is easier to handle and which produces loaves of greater volume than dough made from the same flour to which no potassium bromate has been added. Addition of potassium bromate to flour has been practiced on a small scale, but the practice is increasing. Flour to which potassium bromate has been added is labeled "bromated" and sold exclusively to bakers. The name "bromated flour" is commonly and usually applied to differentiate this product from flour.

22. The amount of potassium bromate added depends on the properties of flour to which it is added, and varies in different crop years. The amount ordinarily used does not exceed 40 parts per million in domestic trade, or 75 parts per million in export trade. An excess of potassium bromate in dough has undesirable effects on bread. A reasonable minimum protein content of the flour used in making bromated flour is 13.5 percent, which is approximately equivalent to 15 percent when calculated to a moisture-free basis.

23. The food commonly and usually known as "self-rising white flour", or "self-rising wheat flour", is prepared by intimately mixing flour, a leavening agent, and salt for seasoning.

24. The leavening agent usually consists of a mixture of sodium bicarbonate and monocalcium phosphate. Sodium acid pyrophosphate, an acid salt of somewhat less neutralizing value than monocalcium phosphate, is sometimes substituted for monocalcium phosphate.

25. When self-rising flour is used in baking, carbon dioxide gas is evolved through the chemical reaction of the sodium bicarbonate and the acid leavening ingredient. The gas so evolved leavens or raises the dough, giving the baked product one of its characteristic qualities. To accomplish this satisfactorily a certain minimum amount of carbon dioxide must be evolved. The amount of carbon dioxide gas which will be effective for the purpose of proper leavening is not less than 0.5 percent of the weight of the self-rising flour.

26. To avoid discoloration and other undesired characteristics in the baked product, the amounts of sodium bicarbonate and acid leavening ingredient must be so proportioned that no sodium bicarbonate remains unacted upon in the baked product. Unnecessarily large amounts of the leavening substances leave objectionable quantities of residues in the baked product. A reasonable maximum limit for the leavening agents in self-rising flour is four and one-half parts to each hundred parts of flour.

27. A satisfactory and reasonably accurate method for determining the amount of carbon dioxide evolved from self-rising flour is the method prescribed in "Official and Tentative Methods of Analysis of the Association of Official Agricultural Chemists", 5th edition, 1940, beginning on page 186 under "Gasometric Method with Chittick's Apparatus—Official", except that the following procedure is substituted for the procedure therein under "6—Determination":

Weigh 17 grams of the official sample into flask A, add 15-20 glass beads (4-6 mm. diameter) and connect this flask with the apparatus (fig. 22). Open stopcock C and by means of the leveling bulb E bring the displacement solution to the 22 cc. graduation above the zero mark. (This 25 cc. is a partial allowance for the volume of acid to be used in the decomposition.) Allow the apparatus to stand 1-2 minutes to insure that the temperature and pressure within the apparatus are the same as those of the room. Close the stopcock, lower the leveling bulb somewhat to reduce the pressure within the apparatus, and slowly run into the decomposition flask from burette F 45 cc. of sulfuric acid (1 + 5). To prevent the liberated carbon dioxide from escaping through the acid burette into the air, keep the displacement solution in the leveling bulb at all times during the decomposition at a lower level than that

in the gas-measuring tube. Rotate and then vigorously agitate the decomposition flask for three minutes to mix the contents intimately. Allow to stand for ten minutes to bring to equilibrium. Equalize the pressure in the measuring tube by means of the leveling bulb and read the volume of gas from the zero point on the tube. Deduct 20 cc. from this reading (this 20 cc. together with previous allowance of 25 cc. compensates for the 45 cc. acid used in the decomposition.) Observe the temperature of the air surrounding the apparatus and also the barometric pressure and multiply the number of cc. of gas evolved by the factor given in Table 24—Chapter XLIII for the temperature and pressure observed. Divide the corrected reading by 100 to obtain the apparent percent by weight of carbon dioxide in the official sample.

Correct the apparent percent of carbon dioxide to compensate for varying atmospheric conditions by immediately assaying a synthetic sample by the same method in the same apparatus.

Prepare the synthetic sample with 16.2 grams of flour, 0.30 gram of monocalcium phosphate, 0.30 gram of salt, and a sufficient quantity of sodium bicarbonate U. S. P. (dried over sulfuric acid) to yield the amount of carbon dioxide recovered in assay of official sample. Determine this quantity by multiplying weight of carbon dioxide recovered in assay of official sample by 1.91.

Divide the weight of carbon dioxide recovered from synthetic sample by weight of carbon dioxide contained in sodium bicarbonate used.

Divide the quotient into the apparent percent of carbon dioxide in official sample to obtain percent carbon dioxide evolved from the official sample.

28. There has recently been placed on the market a self-rising flour containing, in addition to the usual ingredients and in partial substitution for sodium bicarbonate, small amounts of calcium carbonate and light magnesium carbonate. Calcium carbonate and light magnesium carbonate react slowly with the acid ingredient when this self-rising flour is used in baking, but the reaction is incomplete and some calcium carbonate and light magnesium carbonate remain unchanged in the baked product. The method described in Finding 27 for determining the amount of carbon dioxide evolved is unsatisfactory where

carbonates other than sodium bicarbonate are present in self-rising flour.

29. The reason for adding the calcium carbonate is to enrich the diet in calcium and to increase the ratio of calcium to phosphorus. The reason alleged for adding the light magnesium carbonate is that it tends to preserve in the self-rising flour the fluffiness and free flowing qualities characteristic of freshly milled flour.

30. The probable effects of diversity of enrichment of self-rising flour, and of indiscriminate enrichment of foods, are set forth in Findings 36 and 37. In the amount used in this self-rising flour, 0.176 percent, and in amounts up to 0.5 percent light magnesium carbonate causes no observable change in fluffiness, free flowing qualities, or other properties of the self-rising flour.

31. The flour used in preparing self-rising flour is ordinarily bleached prior to mixing with leavening agents and salt. Sometimes the bleaching agent containing benzoyl peroxide, described in Finding 18, is mixed with the flour along with the leavening agents and salt. Findings 18, 19, and 20 apply also to self-rising flour.

32. Flour and self-rising flour are among the principal items of food of the people of the United States. The average consumption is about six and one-half ounces per person per day. This six and one-half ounces supplies about one-fourth of the normal energy requirements of the average person.

33. Recent investigations of the diets of persons in various sections and in various income groups have shown that in many cases the food consumed does not furnish sufficient amounts of certain necessary nutritional elements to maintain health. The deficiencies are more prevalent in the case of persons with low incomes. Such persons usually supply a larger part of their energy requirements from flour and self-rising flour than the average person because of their cheapness as a source of energy.

34. Among the most serious and widespread deficiencies, in children as well as adults, are those of vitamin B_1, riboflavin, nicotinic acid, and iron. Deficiencies of these vitamins tend to occur in the same individuals.

35. A deficiency of calcium exists in certain groups of the population. A deficiency of vitamin D exists in large numbers of infants and children.

36. There have recently been placed on the market

flours and self-rising flours enriched with one or more of the nutritional elements referred to above. These flours vary widely in composition. Unless a standard is promulgated which limits the kinds and amounts of enrichment, the manufacturers' selection of the various nutritive elements and combinations of elements on the basis of economic and merchandising considerations is likely to lead to a great increase in the diversity, both qualitative and quantitative, in enriched flours offered to the public. Such diversity would tend to confuse and mislead consumers as to the relative value of and need for the several nutritional elements, and would impede rather than promote honesty and fair dealing in the interest of consumers.

37. In general, indiscriminate enrichment of foods (including flour and self-rising flour) with vitamins and minerals would tend to confuse and mislead consumers by giving rise to conflicting claims regarding the beneficial effects of such substances, and would be likely to lead to the impression on the part of consumers that a single article of food so enriched would meet all nutritional needs.

38. Limited enrichment of selected staple foods, on the other hand, is readily adapted to the promotion of consumer understanding of the relative value of enriched and natural foods, utilizing such education as consumers have received regarding the nutritive value of natural foods.

39. Essential food elements, now present only in insufficient quantities in many diets, which are present in wheat in considerable quantity, are vitamins of the B complex and iron. Iron (or compounds of iron) and the following vitamins of the B complex are available and suitable for the enrichment of flour and self-rising flour, either in the form of synthetic products or secured from wheat by slight changes in the process of milling flour: vitamin B_1, riboflavin, nicotinic acid or nicotinic acid amide.

40. Vitamin D and calcium are now used singly to a limited extent in the enrichment of flour and self-rising flour. Consumer education has generally recommended dairy products as the most desirable source of calcium and milk as the product most suitable for enrichment with vitamin D in the light of known deficiencies of this element. The addition, however, of vitamin D and calcium as optional ingredients to an enriched flour or enriched self-rising flour will serve a useful purpose for the benefit of persons who do not consume sufficient dairy products.

41. Enrichment of flour or self-rising flour with vitamin A or vitamin C would be unsatisfactory for the reason, among others, that these vitamins are likely to decompose in flour.

42. Stabilized wheat germ oil has been proposed as an optional ingredient of flour for the purpose of increasing the vitamin E content of the flour and for its flavor. The need for the enrichment of foods with vitamin E has not been established. The evidence does not establish that wheat germ oil or stabilized wheat germ oil, in the quantity proposed, has an appreciable effect on the flavor.

43. Pending experience with the use of enriched flour and enriched self-rising flour, consumer education and understanding will be facilitated by restricting the enrichment, not only with respect to the ingredients to be contained therein, but also by the fixing of minimum and maximum amounts of such ingredients. Reasonable limits for this purpose are, for each pound of flour or self-rising flour: not less than 1.66 milligrams nor more than 2.5 milligrams of vitamin B_1, not less than 1.2 milligrams nor more than 1.8 milligrams of riboflavin, not less than 6 milligrams nor more than 24 milligrams of nicotinic acid or nicotinic acid amide, not less than 6 milligrams nor more than 24 milligrams of iron (Fe), not less than 250 U. S. P. units nor more than 1,000 U. S. P. units of vitamin D, and not less than 500 milligrams nor more than 2,000 milligrams of calcium (Ca).

44. Wheat germ, in its natural form or processed to remove part of its oil, is a suitable ingredient for furnishing a part of the requirements for vitamin B_1, riboflavin, nicotinic acid, and iron, but amounts greater than 5 percent in flour or self-rising flour impair the color of the baked product and make it difficult to produce acceptable bread.

45. Iron has been added to flour in the form of harmless and assimilable salts (other harmless and assimilable forms of iron would serve as well). Various harmless and assimilable salts of calcium, including the phosphates, have been used. The use of any of the calcium phosphates results in the introduction of phosphorus in addition to that naturally present in flour, but such introduction is harmless and is thought by some persons to be desirable. Vitamin D has been added to flour as a concentrate of vitamin D in a food oil. When vitamins and iron are added to flour or self-rising flour, their bulk is so small that the use of a

carrier facilitates their intimate and uniform admixture with the flour.

46. Vitamin B_1 in flour and self-rising flour is subject to some loss during baking; the degree of loss increases as the dough decreases in acidity or becomes alkaline. The danger of loss is great when consumers use soda in baking. The addition of monocalcium phosphate safeguards against such losses.

47. Flour and self-rising flour, enriched with vitamins and minerals have not acquired common or usual names; accurate designations for these products are "enriched flour" and "enriched self-rising flour."

48. The reasons for enriching flour with vitamins and minerals are equally applicable to bromated flour. Bromated flour so enriched has not acquired a common or usual name; an accurate designation for this product is "enriched bromated flour."

49. The food commonly and usually known as "durum flour" is manufactured from durum wheat. Durum flour is not ordinarily used for making bread or biscuit but is used for making macaroni and noodles. The purchaser of durum flour expects that it will be suitable for these purposes.

50. Except as above stated the method of preparation of durum flour is the same as that described in Finding 3 with respect to flour. Finding 6 is applicable to durum flour.

51. The charactertistics of durum wheat do not vary to an extent comparable to the variation between hard and soft wheats used for making flour, and a fixed ash limit is satisfactory for distinguishing between durum flours which will make acceptable macaroni and noodles and those which will not. A reasonable ash limit is 1.3 percent, or 1.5 percent when calculated to a moisture-free basis.

52. Findings 12, 13, 15, and 16 are applicable to durum flour.

53. A food is prepared and widely sold in certain parts of the United States consisting of a mixture of flour and monocalcium phosphate, sometimes with the addition of dicalcium phosphate.

54. The primary reason for adding the monocalcium phosphate is to have an excess of acid-reacting material in the dough when such flour is used with soda and sour milk for making biscuit. Dicalcium phosphate also increases the acid-reacting material, but it is far less effective for

this purpose than monocalcium phosphate, and the primary reason for adding it is to enrich the diet in calcium. The probable effects of diversity of enrichment of flour, and of indiscriminate enrichment of foods, are set forth in Findings 36 and 37.

55. Small amounts of monocalcium phosphate will not accomplish the purpose of such addition; too much is likely to impart an undesirable acid taste to products made from such flour. Reasonable limits for monocalcium phosphate are a minimum of 0.25 percent and a maximum of 0.75 percent of the weight of the phosphated flour.

56. Flour to which monocalcium phosphate has been added is commonly labeled "flour—calcium phosphate added." The names "phosphated flour", "phosphated white flour", and "phosphated wheat flour" are commonly and usually applied to differentiate this product from flour.

57. The flour used in preparing phosphated flour is ordinarily bleached prior to mixing with the monocalcium phosphate. Sometimes the bleaching agent containing benzoyl peroxide, described in Finding 18, is mixed with the flour along wtih the monocalcium phosphate. Findings 18, 19, and 20 apply also to phosphated flour.

58. The three foods commonly and usually known as (1) "whole wheat flour", "graham flour", or "entire wheat flour"; (2) "cracked wheat"; (3) "crushed wheat" or "coarse ground wheat", are all made by grinding, cracking, or crushing wheat other than durum wheat or red durum wheat. Consumers generally expect these foods to contain the constituents of the whole wheat berry, other than moisture, in their natural proportions, although in some cases some of the finer material (largely endosperm and germ) or the coarser material (largely bran) is removed, the product often being labeled to show such removal.

59. In the manufacture of these foods the wheat is first cleaned, and is sometimes tempered. Each of these foods contains some moisture. Excessive moisture, however, impairs the keeping qualities and unreasonably increases the weight of these foods. A reasonable limit for moisture, which is not exceeded in good manufacturing practice, is 15 percent.

60. Food products made from the entire wheat berry vary widely in the size of particles. They also vary in the character and shape of the particles, depending on whether the products are made by a grinding or crushing

process or by a cracking or cutting process. A ground or crushed product, even though coarsely ground, contains a substantial amount of fine particles. A cracked or cut product, although it may contain some fine particles, consists chiefly of angular fragments of substantially uniform size.

61. The most finely ground of these products is commonly and usually known as "whole wheat flour", "graham flour", or "entire wheat flour". This product is commonly used for making whole wheat bread, and the purchaser expects it to be suitable for that purpose.

62. In order to make whole wheat bread, whole wheat flour must be of a certain degree of fineness. Reasonable limits for the degree of fineness for this purpose are that at least 90 percent of the whole wheat flour pass through a No. 8 sieve and at least 50 percent of it pass through a No. 20 sieve. Most, though not all, products now sold under the name "whole wheat flour" comply with such limitations.

63. Malted wheat is sometimes mixed with wheat used for making whole wheat flour, or malted wheat flour or malted barley flour is sometimes added to the whole wheat flour, in small amounts so as to compensate for natural deficiencies of enzymes necessary for breadmaking. A reasonable maximum limit for malted wheat flour so used is 0.5 percent, and for malted barley flour so used is 0.25 percent.

64. In the process of milling whole wheat flour, the particles of endosperm sometimes are separated from the ground particles of bran coat and germ of the wheat, and subsequently recombined. In such cases the particles of endosperm are sometimes treated with nitrogen trichloride, chlorine, or a mixture of nitrozyl chloride and chlorine to obtain bleaching and artificial aging effects. Only enough of these agents is used to bring about these effects. Whole wheat flour so treated is labeled "bleached."

65. Products coarser than whole wheat flour, while not suitable for use as the primary ingredient in making bread, are used with flour or whole wheat flour to make special kinds of bread, often designated "cracked wheat bread" and "crushed wheat bread." They are also used to some extent as breakfast foods or an ingredient of certain breakfast foods. In order to be suitable for these purposes the products must be of a certain degree of fineness.

66. Products made by the cracking or cutting process

have a different appearance and different texture from those made by the grinding or crushing process. But considerable confusion now exists in regard to nomenclature of these products, with the result that purchasers of them or of bread containing them are likely to have difficulty in knowing what they are purchasing. Thus, the name "cracked wheat", while it is generally applied to products made by the cracking or cutting process, is also applied occasionally to coarsely ground food products of wheat. The name "cracked wheat" is also applied to animal feed which differs in several respects from products sold for human food, being made up mostly of broken or cracked wheat berries. The fineness of these food products is important in determining their suitability for the purposes stated in Finding 65, and the degree of fineness and of uniformity in the size of particles affords a reasonable method (in addition to the difference in method of manufacture and in shape and character of particles) of differentiating between them.

67. The coarse product made by the grinding process or crushing process is usually sold under the name "crushed wheat", and sometimes as "rolled wheat", or "curled wheat", and occasionally as "cracked wheat." The term "coarse ground wheat" has also been proposed. Reasonable limits on the sizes of the particles of this product, which is suitable for the purposes stated in Finding 65, are that at least 40 percent will pass through a No. 8 sieve, but less than 50 percent will pass through a No. 20 sieve.

68. The coarse product made by the cracking or cutting process is commonly known as "cracked wheat." Reasonable limits on the size of the particles of this product, which is suitable for the purposes stated in Finding 65, are that at least 90 percent will pass through a No. 8 sieve and not more than 20 percent will pass through a No. 20 sieve.

69. A suitable procedure for determining the percentage of these foods which will be retained on or pass through No. 8 and No. 20 sieves is as follows:

Use No. 8 and No. 20 sieves, having standard 8-inch full height frames, complying with the specifications for wire cloth and sieve frames in "Standard Specifications for Sieves," published March 1, 1940, in L. C. 584 of the U. S. Department of Commerce, National Bureau of Standards. Fit a No. 8 sieve into a No. 20 sieve. Attach

bottom pan to the No. 20 sieve. Pour 100 grams of the sample into the No. 8 sieve. Attach cover and hold the assembly in a slightly inclined position with one hand. Shake the sieves by striking the sides against the other hand with an upward stroke, at the rate of about 150 times per minute. Turn the sieves about one-sixth of a revolution, each time in the same direction, after each 25 strokes. Continue shaking for two minutes. Weigh the material which fails to pass through the No. 8 sieve and the material which passes through the No. 20 sieve.

70. A satisfactory and reliable method for the determination of moisture in whole wheat flour is that referred to in Finding 16. This method is well known and widely used in examining whole wheat flour for its moisture content.

71. A satisfactory and reliable method for the determination of moisture in cracked wheat and crushed wheat is that prescribed in the book "Official and Tentative Methods of Analysis of the Association of Official Agricultural Chemists," 4th Edition, 1935, page 335, under the caption "Preparation of Sample—Official" and "Moisture I. Drying with Heat—Official." The same method has recently been republished in the book "Official and Tentative Methods of Analysis of the Association of Official Agricultural Chemists," 5th edition, 1940, page 353, under "Preparation of Sample—Official" and "Moisture I. Drying with Heat—Official." This method is well known and widely used in examining crushed wheat and cracked wheat for their moisture content.

72. The reasons for adding potassium bromate to flour, and the amounts in which it is added, stated in Findings 21 and 22, are equally applicable to whole wheat flour. Whole wheat flour to which potassium bromate is added is labeled "bromated"; an accurate designation for the product is "bromated whole wheat flour."

73. The food known as "whole durum wheat flour" is prepared from durum wheat by the same process employed in making whole wheat flour (Findings 59, 62, 63, 64, and 65), and is used in making certain kinds of bread. Consumers generally expect whole durum wheat flour to contain the constituents of the whole durum wheat berry, other than moisture, in their natural proportions. A reasonable moisture limit and reasonable granulation limits for whole durum wheat flour are the same as for whole wheat flour.

74. The food commonly and usually known as "farina"

is manufactured from wheat, either hard or soft, other than durum wheat and red durum wheat.

75. In making farina the wheat is first cleaned. It is usually tempered. It is then ground, bran coat and germ are separated from the endosperm, and the flour is removed by bolting. Farina consists essentially of endosperm; but the particles of farina are larger than those of flour. The size of the particles of farina has become well established through usage, and is a distinguishing characteristic of the product. The size is such that farina will pass through a No. 20 sieve but that only a small amount will pass through a No. 100 sieve. The material passing through the No. 100 sieve comes mostly from abrasion of particles of farina during handling after it is manufactured. A reasonable limit for this fine material is 3.0 percent.

76. A satisfactory method for testing farina for size of particles is as follows:

Use No. 20 and No. 100 sieves, having standard 8-inch full height frames, complying with the specifications for wire cloth and sieve frames in "Standard Specifications for Sieves", published March 1, 1940, in L. C. 584 of the U. S. Department of Commerce, National Bureau of Standards. Fit a No. 20 sieve into a No. 100 sieve. Attach bottom pan to the No. 100 sieve. Four 100 grams of the sample into the No. 20 sieve. Attach cover and hold the assembly in a slightly inclined position with one hand. Shake the sieves by striking the sides against the other hand with an upward stroke, at the rate of about 150 times per minute. Turn the sieves about one-six of a revolution, each time in the same direction, after each 25 strokes. Continue shaking for two minutes. Weigh the material which fails to pass through the No. 20 sieve and the material which passes through the No. 100 sieve.

77. Consumers generally expect farina to be almost entirely free from bran coat and germ. In this respect it corresponds substantially to "patent flour." The extent of removal can be measured by the percent of ash in the farina (see Finding 6). A generally recognized and reasonable maximum limit for ash is about 0.5 percent, or not more than 0.6 percent on a moisture-free basis.

78. All farina contains some moisture. Excessive moisture impairs the keeping qualities of farina and unnecessarily increases its weight. A reasonable limit for mois-

ture, which is not exceeded in good milling practice, is 15 percent.

79. A satisfactory and reliable method for the determination of the ash content of farina is that referred to in Finding 15. A satisfactory and reliable method for the determination of the moisture content of farina is that referred to in Finding 16. These methods are well-known and widely used.

80. The removal of bran coat and germ from endosperm in the manufacture of farina removes those parts of the wheat which are richest in vitamins and minerals.

81. Farina is used as a breakfast food and as an ingredient of macaroni products. It is not as widely consumed as flour, but it is extensively used as a cereal food for children and in many cases is the only cereal food used during a period of their growth.

82. Certain manufacturers are now selling farina to which have been added vitamins and minerals. Ingredients now being added for this purpose are vitamin D contained in dried irradiated yeast (other sources of vitamin D would serve equally well), and portions of the vitamin B complex and minerals contained in freshly milled wheat germ or wheat germ from which part of the oil has been removed. Iron and calcium have also been added in the form of assimilable salts, which are available and suitable for the purpose. In addition to wheat germ other sources of members of the vitamin B complex are available and suitable.

83. In general, the interest of consumers is affected by the enrichment of farina with vitamins and minerals in the same way as has been outlined in connection with the enrichment of flour in Findings 34 to 43, inclusive.

84. Because of the small quantities in which farina is ordinarily consumed, and because of its special use in diets of some children, there is occasion for the enrichment of farina with quantities of vitamins and minerals substantially in excess of the reasonable maxima for flour. Findings 44 and 45 are applicable to farina, except that farina is not used for making bread and a reasonable limit for the wheat germ is 8 percent.

85. The time necessary for cooking enriched farina can be shortened by the addition of from one-half to one per cent of disodium phosphate.

86. Farina enriched with vitamins and minerals has

not acquired a common or usual name; an accurate designation for the product is "enriched farina."

87. The food commonly and usually known as semolina is manufactured from durum wheat.

88. In making semolina the wheat is first cleaned. It is usually tempered. It is then ground, the bran coat and germ are separated from the endosperm, and durum flour is removed by bolting. Semolina consists essentially of the endosperm, but the particles of semolina are larger than those of durum flour. The size of the particles of semolina has become well established through usage, and is a distinguishing characteristic of the product. The size is such that semolina will pass through a No. 20 sieve but that only a small amount will pass through a No. 100 sieve. The material passing through the No. 100 sieve comes mostly from abrasion of particles of semolina during handling after it is manufactured. A reasonable limit for this fine material is 3.0 percent.

89. A satisfactory method for testing semolina for size of particles is the method described in Finding 76.

90. Semolina is used in the manufacture of macaroni and noodles, and sometimes as a breakfast food. Consumers generally expect semolina to be almost entirely free from bran coat and germ. The extent of the removal can be measured by the percent of ash in the semolina (see Finding 6). A generally recognized and reasonable limit for ash is about 0.8 percent or not more than 0.92 percent on a moisture-free basis.

91. All semolina contains some moisture. Excessive moisture impairs the keeping qualities of semolina and unnecessarily increases its weight. A reasonable limit for moisture, which is not exceeded in good manufacturing practice, is 15 percent.

92. A satisfactory and reliable method for the determination of the ash content of semolina is that referred to in Finding 15. A satisfactory and reliable method for determination of the moisture content of semolina is that referred to in Finding 16. These methods are well-known and widely used.

On the basis of the foregoing findings of fact it is concluded that each of the following regulations fixing and establishing a definition and standard of identity for a food will promote honesty and fair dealing in the interest of consumers:

Regulations.

§ 15.000 Flour, white flour, wheat flour, plain flour—identity; label statement of optional ingredients. (a) Flour, white flour, wheat flour, plain flour, is the food prepared by grinding and bolting cleaned wheat other than durum wheat and red durum wheat, to compensate for any natural deficiency of enzymes, malted wheat, malted wheat flour, malted barley flour, or any combination of two or more of these, may be used; but the quantity of malted barley flour so used is not more than 0.25 percent. One of the cloths through which the flour is bolted has openings not larger than those of woven wire cloth designated "149 micron (No. 100)" in table I of "Standard Specifications for Sieves", published March 1, 1940, in L. C. 584 of the U. S. Department of Commerce, National Bureau of Standards. The flour is freed from bran coat, or bran coat and germ, to such extent that the percent of ash therein, calculated to a moisture-free basis, is not more than the sum of one-twentieth of the percent of protein therein, calculated to a moisture-free basis, and 0.35. Its moisture content is not more than 15 percent. Unless such addition conceals damage or inferiority of the flour or makes it appear better or of greater value than it is, one or any combination of two or more of the following optional bleaching ingredients may be added in a quantity not more than sufficient for bleaching or, in case such ingredient has an artificial aging effect, in a quantity not more than sufficient for bleaching and such artificial aging effect:

(1) oxides of nitrogen,
(2) chlorine,
(3) nitrosyl chloride,
(4) nitrogen trichloride,
(5) one part by weight of benzoyl peroxide mixed with not more than six parts by weight of a mixture of either potassium alum or calcium sulfate and magnesium carbonate.

(b) When any optional bleaching ingredient is used, the label shall bear the word "Bleached." Wherever the name of the food appears on the label so conspicuously as to be easily seen under customary conditions of purchase, the word "Bleached" shall immediately and conspicuously precede or follow such name, without inter-

vening written, printed, or graphic matter; except that where such name is a part of a trade-mark or brand, other written, printed, or graphic matter, which is also a part of such trade-mark or brand, may so intervene if the word "Bleached" is in such juxtaposition with such trade-mark or brand as to be conspicuously related to such name.

(c) For the purposes of this section:

(1) Ash is determined by the method prescribed in the book "Official and Tentative Methods of Analysis of the Association of Official Agricultural Chemists", 5th edition, 1940, page 212, under "Method I—Official." Ash is calculated to a moisture-free basis by subtracting the percent of moisture in the flour from 100, dividing the remainder into the percent of ash, and multiplying the quotient by 100.

(2) Protein is 5.7 times the nitrogen as determined by the method prescribed in such book on page 26, under "Kjeldahl-Gunning-Arnold Method—Official." Protein is calculated to a moisture-free basis by subtracting the percent of moisture in the flour from 100, dividing the remainder into the percent of protein, and multiplying the quotient by 100.

(3) Moisture is determined by the method prescribed in such book on page 211, under "Vacuum Oven Method—Official."

§ 15.910 Enriched flour—identity; label statement of optional ingredients. Enriched flour conforms to the definition and standard of identity, and is subject to the requirements for label statement of optional ingredients, prescribed for flour by § 15.000, except that:

(a) it contains in each pound not less than 1.66 milligrams and not more than 2.5 milligrams of vitamin B_1, not less than 1.2 milligrams and not more than 1.8 milligrams of riboflavin, not less than 6 milligrams and not more than 24 milligrams of nicotinic acid or nicotinic acid amide, not less than 6 milligrams and not more than 24 milligrams of iron (Fe);

(b) vitamin D may be added in such quantity that each pound of the finished enriched flour contains not less than 250 U. S. P. units and not more than 1,000 U. S. P. units of vitamin D;

(c) calcium may be added in such quantity that each

* §§ 15.000 to 15.150, inclusive, issued under the authority contained in 52 Stat. 1046, 53 Stat. 1077; 21 U. S. C., Sup. 341, 5 U. S. C., Sup. 133-133t and Reorganization Plans Nos. I and IV; 4 F. R. 2727, 5 F. R. 2421.

pound of the finished enriched flour contains not less than 500 milligrams and not more than 2,000 milligrams of calcium (Ca), except that enriched flour may be acidified with monocalcium phosphate irrespective of the minimum limit for calcium (Ca) herein prescribed;

(d) it may contain not more than 5 percent by weight of wheat germ or partly defatted wheat germ; and

(e) in determining whether the ash content complies with the requirements of this section allowance is made for ash resulting from any added iron or salts of iron or calcium.

Iron and calcium may be added only in forms which are harmless and assimilable. The substances referred to in paragraphs (a) and (b) may be added in a harmless carrier which does not impair the enriched flour; such carrier is used only in the quantity necessary to effect an intimate and uniform admixture of such substances with the flour.*

§ 15.020 Bromated flour—identity; label statement of optional ingredients. Bromated flour conforms to the definition and standard of identity, and is subject to the requirements for label statement of optional ingredients, prescribed for flour by § 15.000, except that:

(a) potassium bromate is added in a quantity not exceeding 75 parts to each million parts of the finished bromated flour; and

(b) its protein content, calculated to a moisture-free basis, is not less than 15 percent (determination and calculations of protein are made as prescribed in § 15.000 (c) (2)).*

§ 15.030 Enriched bromated flour—identity; label statement of optional ingredients. Enriched bromated flour conforms to the definition and standard of identity, and is subject to the requirements for label statement of optional ingredients, prescribed for enriched flour by § 15.010, except that:

(a) potassium bromate is added in a quantity not exceeding 75 parts to each million parts of the finished enriched bromated flour; and

(b) its protein content, calculated to a moisture-free basis, is not less than 15 percent (determination and calculations of protein are made as prescribed in § 15.000 (c) (2)).*

* §§ 15.000 to 15.150, inclusive, issued under the authority contained in 52 Stat. 1046, 53 Stat. 861ff; 21 U. S. C., Sup. 341, 5 U. S. C., Sup. 133-133t and Reorganization Plans Nos. I and IV, 4 F. R. 2727, 5 F. R. 2421.

§ 15.040 Durum flour—identity. (a) Durum flour is the food prepared by grinding and bolting cleaned durum wheat. One of the cloths through which such flour is bolted has openings not larger than those of woven wire cloth designated "149 micron (No. 100)" in table I of "Standard Specifications for Sieves," published March 1, 1940, in L. C. 584 of the U. S. Department of Commerce, National Bureau of Standards. It is freed from bran coat, or bran coat and germ, to such extent that the percent of ash therein, calculated to a moisture-free basis, is not more than 1.5 percent. Its moisture content is not more than 15 percent.

(b) For the purposes of this section, ash and moisture are determined by the methods therefor referred to in § 15.000 (c).*

§ 15.050 Self-rising flour, self-rising white flour, self-rising wheat flour—identity; label statement of optional ingredients. (a) Self-rising flour, self-rising white flour, self-rising wheat flour, is an intimate mixture of flour, sodium bicarbonate, and the acid-reacting substance monocalcium phosphate or sodium acid pyrophosphate or both. It is seasoned with salt. When it is tested by the method prescribed in subsection (c), not less than 0.5 percent of carbon dioxide is evolved. The acid-reacting substance is added in sufficient quantity to neutralize the sodium bicarbonate. The combined weight of such acid-reacting substance and sodium bicarbonate is not more than 4.5 parts to each 100 parts of flour used. Subject to the conditions and restrictions prescribed by § 15.000 (a), the bleaching ingredients specified in such section may be added as optional ingredients. If the flour used in making the self-rising flour is bleached, the optional bleaching ingredient used therein (see § 15.000 (a)) is also an optional ingredient of the self-rising flour.

(b) When any optional bleaching ingredient is used, the label shall bear the word "Bleached." Wherever the name of the food appears on the label so conspicuously as to be easily seen under customary conditions of purchase, the word "Bleached" shall immediately and conspicuously precede or follow such name, without intervening written, printed, or graphic matter; except that where such name is a part of a trade-mark or brand, other written, printed, or graphic matter, which is also a part of such trade-mark or

* §§ 15.000 to 15.150, inclusive, issued under the authority contained in 52 Stat. 1046, 53 Stat. 861ff; 21 U. S. C., Sup. 341, 5 U. S. C., Sup. 133-133t and Reorganization Plans Nos. I and IV, 4 F. R. 2727, 5 F. R. 2421.

brand, may so intervene if the word "Bleached" is in such juxtaposition with such trade-mark or brand as to be conspicuously related to such name.

(c) The method referred to in paragraph (a) is the method prescribed in "Official and Tentative Methods of Analysis of the Association of Official Agricultural Chemists," 5th edition, 1940, beginning on page 186 under "Gasometric Method with Chittick's Apparatus—Official," except that the following procedure is substituted for the procedure specified therein under "6—Determination":

Weigh 17 grams of the official sample into flask A, add 15-20 glass beads (4-6 mm. diameter), and connect the flask with the apparatus (fig. 22). Open stopcock C and by means of the leveling bulb E bring the displacement solution to the 25 cc. graduation above the zero mark. (This 25 cc. is a partial allowance for the volume of acid to be used in the decomposition.) Allow the apparatus to stand 1-2 minutes to insure that the temperature and pressure within the apparatus are the same as those of the room. Close the stopcock, lower the leveling bulb somewhat to reduce the pressure within the apparatus, and slowly run into the decomposition flask from burette F 45 cc. of sulfuric acid (1+5). To prevent the liberated carbon dioxide from escaping through the acid burette into the air, keep the displacement solution in the leveling bulb at all times during the decomposition at a lower level than that in the gas-measuring tube. Rotate and then vigorously agitate the decomposition flask for three minutes to mix the contents intimately. Allow to stand for ten minutes to bring to equilibrium. Equalize the pressure in the measuring tube by means of the leveling bulb and read the volume of gas from the zero point on the tube. Deduct 20 cc. from this reading (this 20 cc. together with previous allowance of 25 cc. compensates for the 45 cc. acid used in the decomposition). Observe the temperature of the air surrounding the apparatus and also the barometic pressure and multiply the number of cc. of gas evolved by the factor given in table 24—Chapter XLIII for the temperature and pressure observed. Divide the corrected reading by 100 to obtain the apparent percent by weight of carbon dioxide in the official sample.

Correct the apparent percent of carbon dioxide to compensate for varying atmospheric conditions by immediately assaying a synthetic sample by the same method in the same apparatus.

Prepare the synthetic sample with 16.2 grams of flour, 0.30 gram of monocalcium phosphate, 0.30 gram of salt, and a sufficient quantity of sodium bicarbonate U. S. P. (dried over sulfuric acid) to yield the amount of carbon dioxide recovered in assay of official sample. Determine this quantity by multiplying weight of carbon dioxide recovered in assay of official sample by 1.91.

Divide the weight of carbon dioxide recovered from synthetic sample by weight of carbon dioxide contained in sodium bicarbonate used.

Divide the quotient into the apparent percent of carbon dioxide in official sample to obtain percent of carbon dioxide evolved from the official sample.*

§ 15.060 Enriched self-rising flour—identity; label statement of optional ingredients. Enriched self-rising flour conform to the definition and standard of identity, and is subject to the requirements for label statement of optional ingredients, prescribed for self-rising flour by § 15.050, except that:

(a) it contains in each pound not less than 1.66 milligrams and not more than 2.5 milligrams of vitamin B_1, not less than 1.2 milligrams and not more than 1.8 milligrams of riboflavin, not less than 6 milligrams and not more than 24 milligrams of nicotinic acid or nicotinic acid amide, not less than 6 milligrams and not more than 24 milligrams of iron (Fe);

(b) vitamin D may be added in such quantity that each pound of the finished enriched self-rising flour contains not less than 250 U. S. P. units and not more than 1,000 U. S. P. units of vitamin D;

(c) calcium may be added in such quantity that each pound of the finished enriched self-rising flour contains not less than 500 milligrams and not more than 2,000 milligrams of calcium (Ca);

(d) it may contain not more than 5 percent by weight of wheat germ or partly defatted wheat germ;

(e) when calcium is added as dicalcium phosphate, such dicalcium phosphate is also considered to be an acid-reacting substance; and

(f) when calcium is added as carbonate, the method set forth in § 15.040 (c) does not apply as a test for carbon

* §§ 15.000 to 15.150, inclusive, issued under the authority contained in 52 Stat. 1046, 53 Stat. 561ff; 21 U. S. C., Sup. 341, 5 U. S. C., Sup. 133-133t and Reorganization Plans Nos. I and IV, 4 F. R. 2727, 5 F. R. 2421.

dioxide evolved; but in such case the quantity of carbon dioxide evolved under ordinary conditions of use of the enriched self-rising flour is not less than 0.5 percent of the weight thereof.

Iron and calcium may be added only in forms which are harmless and assimilable. The substances referred to in paragraphs (a) and (b) may be added in a harmless carrier which does not impair the enriched self-rising flour; such carrier is used only in the quantity necessary to effect an intimate and uniform admixture of such substances with the flour.*

§ 15.075 Phosphated flour, phosphated white flour, phosphated wheat flour—identity; label statement of optional ingredients. Phosphated flour, phosphated white flour, phosphated wheat flour, conforms to the definition and standard of identity, and is subject to the requirements for label declaration of optional ingredients, prescribed for flour by § 15.000, except that:

(a) monocalcium phosphate is added in a quantity not less than 0.25 percent and not more than 0.75 percent of the weight of the finished phosphated flour; and

(b) in determining whether the ash content complies with the requirements of this regulation allowance is made for the added monocalcium phosphate.*

§ 15.080 Whole wheat flour, graham flour, entire wheat flour—identity; label statement of optional ingredients. (a) Whole wheat flour, graham flour, entire wheat flour, is the food prepared by so grinding cleaned wheat other than durum wheat and red durum wheat that, when tested by the method prescribed in subsection (c) (2), not less than 90 percent passes through a No. 8 sieve and not less than 50 percent passes through a No. 20 sieve. The proportions of the natural constituents of such wheat, other than moisture, remain unaltered. To compensate for any natural deficiency of enzymes, malted wheat, malted wheat flour, malted barley flour, or any combination of two or more of these, may be used; but the quantity of malted wheat flour so used is not more than 0.5 percent, and the quantity of malted barley flour so used is not more than 0.25 percent. The moisture content of whole wheat flour is not more than 15 percent. Unless such addition conceals damage or in-

* §§ 15.000 to 15.150, inclusive, issued under the authority contained in 52 Stat. 1046, 53 Stat. 1077; 21 U. S. C., Sup. 341, 5 U. S. C., Sup. 133-133 and Reorganization Plans Nos. I and IV, 4 F. R. 2727, 5 F. R. 2421.

feriority of the whole wheat flour or makes it appear better or of greater value than it is, the optional bleaching ingredient nitrogen trichloride, chlorine, or a mixture of nitrosyl chloride and chlorine, may be added in a quantity not more than sufficient for bleaching and artificial aging effects.

(b) When any optional bleaching ingredient is used, the label shall bear the word "Bleached." Wherever the name of the food appears on the label so conspicuously as to be easily seen under customary conditions of purchase, the word "Bleached" shall immediately and conspicuously precede or follow such name, without intervening written, printed, or graphic matter; except that where such name is a part of a trade-mark or brand, other written, printed, or graphic matter, which is also a part of such trade-mark or brand, may so intervene if the word "Bleached" is in such juxtaposition with such trade-mark or brand as to be conspicuously related to such name.

(c) For the purpose of this section:

(1) Moisture is determined by the method prescribed in "Official and Tentative Methods of Analysis of the Association of Official Agricultural Chemists", 5th edition, 1940, page 211; under "Vacuum Oven Method—Official."

(2) The method referred to in paragraph (a) is as follows: Use No. 8 and No. 20 sieves, having standard 8-inch full height frames, complying with the specifications for wire cloth and sieve frames in "Standard Specifications for Sieves", published March 1, 1940, in L. C. 584 of the U. S. Department of Commerce, National Bureau of Standards. Fit a No. 8 sieve into a No. 20 sieve. Attach bottom pan to the No. 20 sieve. Pour 100 grams of the sample into the No. 8 sieve. Attach cover and hold the assembly in a slightly inclined position with one hand. Shake the sieves by striking the sides against the other hand with an upward stroke, at the rate of about 150 times per minute. Turn the sieves about one-sixth of a revolution, each time in the same direction, after each 25 strokes. Continue shaking for two minutes. Weigh the material which fails to pass through the No. 8 sieve and the material which passes through the No. 20 sieve.*

§ 15.090 Bromated whole wheat flour—identity; label

* §§ 15.000 to 15.150, inclusive, issued under the authority contained in 52 Stat. 1046, 53 Stat. 561ff; 21 U. S. C., Sup. 341, 5 U. S. C., Sup. 133-133i and Reorganization Plans Nos. I and IV, 4 F. R. 2727, 5 F. R. 2421.

statement of optional ingredients. Bromated whole wheat flour conforms to the definition and standard of identity, and is subject to the requirements for label statement of optional ingredients, prescribed for whole wheat flour by § 15.080, except that potassium bromate is added in a quantity not exceeding 75 parts to each million parts of finished bromated whole wheat flour.*

§ 15.100 Whole durum wheat flour—identity: label statement of optional ingredients. Whole durum wheat flour conforms to the definition and standard of identity, and is subject to the requirements for label statement of optional ingredients, prescribed for whole wheat flour by § 15.080, except that cleaned durum wheat, instead of cleaned wheat other than durum wheat and red durum wheat, is used in its preparation.*

§ 15.110 Crushed wheat, coarse ground wheat—identity. Crushed wheat, coarse ground wheat, is the food prepared by so crushing cleaned wheat other than durum wheat and red durum wheat that, when tested by the method prescribed in § 15.080 (c) (2), 40 percent or more passes through a No. 8 sieve and less than 50 percent passes through a No. 20 sieve. The proportions of the natural constituents of such wheat, other than moisture, remain unaltered. Crushed wheat contains not more than 15 percent of moisture as determined by the method prescribed in "Official and Tentative Methods of Analysis of the Association of Official Agricultural Chemists", 5th edition, 1940, page 353, under "Preparation of Sample—Official" and "Moisture I. Drying with Heat—Official."*

§ 15.120 Cracked wheat—identity. Cracked wheat is the food prepared by so cracking or cutting into angular fragments cleaned wheat other than durum wheat and red durum wheat that, when tested by the method prescribed in § 15.080 (c) (2), not less than 90 percent passes through a No. 8 sieve and not more than 20 percent passes through a No. 20 sieve. The proportions of the natural constituents of such wheat, other than moisture, remain unaltered. Cracked wheat contains not more than 15 percent of moisture as determined by the method prescribed in "Official and Tentative Methods of Analysis of the Association of Official Agricultural Chemists", 5th edition, 1940, page 353.

* §§ 15.000 to 15.150, inclusive, issued under the authority contained in 52 Stat. 1046, 53 Stat. 1433; 21 U. S. C., Sup. 341, 5 U. S. C., Sup. 133-133t and Reorganization Plans Nos. I and IV, 4 F. R. 2727, 5 F. R. 2421.

under "Preparation of Sample—Official" and "Moisture I. Drying with Heat—Official." *

§ 15.130 Farina—identity. (a) Farina is the food prepared by grinding and bolting cleaned wheat, other than durum wheat and red durum wheat, to such fineness that, when tested by the method prescribed in paragraph (b) (2), it passes through a No. 20 sieve, but not more than 3 percent passes through a No. 100 sieve. It is freed from bran coat, or bran coat and germ, to such extent that the percent of ash therein, calculated to a moisture-free basis, is not more than 0.6 percent. Its moisture content is not more than 15 percent.

(b) For the purposes of this section:

(1) Ash and moisture are determined by the methods therefor referred to in § 15.000 (c).

(2) The method referred to in paragraph (a) is as follows: Use No. 20 and No. 100 sieves, having standard 8-inch full height frames, complying with the specifications for wire cloth and sieve frames in "Standard Specifications for Sieves," published March 1, 1940, in L. C. 584 of the U. S. Department of Commerce, National Bureau of Standards. Fit a No. 20 sieve into a No. 100 sieve. Attach bottom pan to the No. 100 sieve. Pour 100 grams of the sample into the No. 20 sieve. Attach cover and hold the assembly in a slightly inclined position with one hand. Shake the sieves by striking the sides against the other hand with an upward stroke, at the rate of about 150 times per minute. Turn the sieves about one-sixth of a revolution, each time in the same direction, after each 25 strokes. Continue shaking for two minutes. Weigh the material which fails to pass through the No. 20 sieve and the material which passes through the No. 100 sieve.*

§ 15.140 Enriched farina—identity; label statement of optional ingredients. (a) Enriched farina conforms to the definition and standard of identity prescribed for farina by § 15.130, except that:

(1) it contains in each pound not less than 1.66 milligrams of vitamin B_1, not less than 1.2 milligrams of riboflavin, not less than 6 milligrams of nicotinic acid or nicotinic acid amide, and not less than 6 milligrams of iron (Fe);

* §§ 15.000 to 15.150, inclusive, issued under the authority contained in 52 Stat. 1046, 53 Stat. 1783; 21 U. S. C., Sup. 341, 5 U. S. C., Sup. 133-133t and Reorganization Plans Nos. I and IV, 4 F. R. 2727, 5 F. R. 2421.

(2) vitamin D may be added in such quantity that each pound of the finished enriched farina contains not less than 250 U. S. P. units of the optional ingredient vitamin D;

(3) Calcium may be added in such quantity that each pound of the finished enriched farina contains not less than 500 milligrams of the optional ingredient calcium (Ca);

(4) it may contain not more than 8 percent by weight of the optional ingredient wheat germ or partly defatted wheat germ;

(5) it may contain not less than 0.5 percent and not more than 1 percent by weight of the optional ingredient disodium phosphate; and

(6) In determining whether the ash content complies with the requirements of this regulation allowance is made for ash resulting from any added iron or salts of iron or calcium, or from any added disodium phosphate, or from any added wheat germ or partly defatted wheat germ.

Iron and calcium may be added only in forms which are harmless and assimilable. Dried irradiated yeast may be used as a source of vitamin D. The substances referred to in subparagraphs (1) and (2) may be added in a harmless carriet which does not impair the enriched farina; such carrier is used only in the quantity necessary to effect an intimate and uniform admixture of such substances with the farina.

(b) When the optional ingredient disodium phosphate is used, the label shall bear the statement "Disodium phosphate added for quick cooking." Whenever the name of the food appears on the label so conspicuously as to be easily seen under customary conditions of purchase, such statement shall immediately and conspicuously precede or follow such name, without intervening written, printed, or graphic matter; except that where such name is a part of a trade-mark or brand, other written, printed, or graphic matter, which is also a part of such trade-mark or brand, may so intervene if such statement is in such juxtaposition with such trade-mark or brand as to be conspicuously related to such name.*

§ 15.150 Semolina—identity. (a) Semolina is the food prepared by grinding and bolting cleaned durum wheat to such fineness that, when tested by the method prescribed in

* §§ 15.000 to 15.150, inclusive, issued under the authority contained in 52 Stat. 1046, 53 Stat. 861ff; 21 U. S. C., Sup. 341, 5 U. S. C., Sup. 133-133t and Reorganization Plans Nos. I and IV, 4 F. R. 2727, 5 F. R. 2421.

§ 15.130 (b) (2), it passes through a No. 20 sieve, but not more than 3 percent passes through a No. 100 sieve. It is freed from bran coat, or bran coat and germ, to such extent that the percent of ash therein, calculated to a moisture-free basis, is not more than 0.92 percent. Its moisture content is not more than 15 percent.

(b) For the purpose of this section:

Ash and moisture are determined by the methods therefor referred to in § 15.000 (c).*

This order shall become effective on January 1, 1942.

Washington, D. C., May 26, 1941.

W. B. Miller,
Acting Administrator.

(Seal)

[F. R. Doc. 41-3761; Filed, May 26, 1941; 11:57 a. m.]

UNITED STATES CIRCUIT COURT OF APPEALS

For the Seventh Circuit.

The Quaker Oats Company, *Petitioner.*
vs.
Federal Security Administrator, *Respondent.*
} Number 7765.

CERTIFICATION OF RECORD.

I hereby certify that the attached papers are the transcript of the proceedings and the record on which was based the order dated May 26, 1941 (6 Fed. Reg. 2574-2582), fixing and establishing definitions and standards of identity for enriched farina and related foods. Certain of the briefs and exceptions filed against the order which relate exclusively to parts thereof not under review in this proceeding are not included with the record certified.

Wilson B. Miller,
Assistant Federal Security Administrator.

(Seal)

Washington, D. C., September 26, 1941.

* §§ 15.000 to 15.150, inclusive, issued under the authority contained in 52 Stat. 1046, 53 Stat. 561ff; 21 U. S. C., Sup. 341, 5 U. S. C., Sup. 133-133l and Reorganization Plans Nos. I and IV, 4 F. R. 2727, 5 F. R. 2421.

Filed Aug. 22, 1941.

UNITED STATES CIRCUIT COURT OF APPEALS

For the Seventh Circuit.

The Quaker Oats Company, *Petitioner,*
vs.
Federal Security Administrator, *Respondent.*
} Number 7765.

PETITION FOR REVIEW OF ORDER OF THE FEDERAL SECURITY ADMINISTRATOR.

To the Honorable, the Judges of the United States Circuit Court of Appeals for the Seventh Circuit:

There being an actual controversy as to the validity of a certain Order of the Federal Security Administrator, The Quaker Oats Company, a corporation, being adversely affected by the said certain Order of the Federal Security Administrator dated May 26, 1941, and published in the Federal Register on May 27, 1941, a copy of which Order is attached hereto, marked "Exhibit A," and hereby made a part hereof, fixing and establishing a definition and standard of identity for Farina and for Enriched Farina, files this Petition to review said Order and respectfully represents unto the Court:

1. Petitioner, The Quaker Oats Company, is a corporation organized and existing under and by virtue of the laws of the State of New Jersey, having its principal place of business in the City of Chicago, County of Cook and State of Illinois.

2. The principal place of business of Petitioner, The Quaker Oats Company, is within the Seventh Judicial Circuit of the United States.

3. The Petitioner, The Quaker Oats Company, is one of the largest manufacturers of farina in the United States, which, since 1932, it has sold, advertised and distributed under the name "Quaker Farina Wheat Cereal Enriched with Vitamin D," or "Quaker Farina Enriched by the Sunshine Vitamin."

4. The Respondent, Federal Security Administrator, made and entered the said Order complained of pursuant to authority granted him by an Act of Congress of June 25,

1938, (C. 675, Sec. 1; 52 Stat. 1040; 21 U. S. C. A. 301) known as the Federal Food, Drug & Cosmetic Act, and in pursuance of Reorganization Plan No. IV which, effective June 30, 1940, transferred the Food & Drug Administration in the Department of Agriculture to the Federal Security Agency and provided that said Administration should be administered under the direction and supervision of the Federal Security Administrator. This Honorable Court has jurisdiction over the parties hereto and of the subject matter hereof under Section 701 of the said Federal Food, Drug & Cosmetic Act.

5. Pursuant to notice, public hearings were held by Respondent, Federal Security Administrator, to receive evidence relating to the definition and standard of identity for Farina proposed by the Federal Security Administrator.

6. Although evidence was introduced at said public hearings showing that Petitioner has added Vitamin D to Farina for many years and that Farina with the addition of Vitamin D is an improved product, said Order does not permit the addition of Vitamin D as an optional ingredient in Farina.

7. Although evidence was introduced at said public hearings establishing the fact that The Quaker Oats Company has, since 1932, manufactured, sold, advertised and distributed a product known as "Quaker Farina Wheat Cereal Enriched with Vitamin D" or "Quaker Farina Enriched By The Sunshine Vitamin," the Federal Security Administrator filed said Order, the effect of which will prevent and preclude The Quaker Oats Company from selling and distributing said product under said name or under any name employing the word "Farina," regardless of the fact that the said product is accurately described as "Farina Enriched with Vitamin D" and is a wholesome, nutritious product for which there is a large consumer demand.

8. No notice of public hearings was given by the Federal Security Administrator, and no public hearings were held as required by said Federal Food, Drug & Cosmetic Act, relative to the definition and standard of identity for Enriched Farina.

9. Despite the failure of the Respondent, Federal Security Administrator, to give notice of and to hold public hearings relative to the definition and standard of identity for Enriched Farina, and despite the absence of evidence

concerning such product, the Federal Security Administrator established in said Order a definition and standard of identity for Enriched Farina.

Statement of Points.

Petitioner alleges that said Order dated May 26, 1941, and published in the Federal Register on May 27, 1941, is erroneous, unreasonable and unlawful for the following reasons:

(a) Because said Order destroys the long established business of The Quaker Oats Company in its product "Quaker Farina Wheat Cereal Enriched with Vitamin D," in violation of the Fifth Amendment to the Constitution and contrary to the intent, purposes and provisions of the Federal Food, Drug & Cosmetic Act.

(b) Because the effect of said Order is to prohibit the manufacture and sale of a product composed of Farina and Vitamin D and called "Farina Enriched with Vitamin D" or by any other name employing the word "Farina," in violation of the Fifth Amendment to the Constitution and contrary to the intent, purposes and provisions of the Federal Food, Drug & Cosmetic Act.

(c) Because the effect of said Order is to deprive the public of a wholesome, nutritious product for which there is a large consumer demand, contrary to the intent, purposes and provisions of the Federal Food, Drug & Cosmetic Act.

(d) Because the Respondent, Federal Security Administrator, in disregard of the evidence that Vitamin D should be included as an optional ingredient in Farina did not in his Order include Vitamin D as an optional ingredient in Farina, contrary to the provisions of the Federal Food, Drug & Cosmetic Act.

(e) Because said Order is not based upon substantial evidence of record at the hearings, and is not supported by competent and substantial evidence, contrary to the provisions of the Federal Food, Drug & Cosmetic Act.

(f) Because Respondent, Federal Security Administrator, established a definition and standard of identity for Enriched Farina respecting which said product no notice of public hearings was given as required by said Federal Food, Drug & Cosmetic Act.

(g) Because Respondent, Federal Security Administrator, established a definition and standard of identity for Enriched Farina, respecting which said product no public

hearings were held and no evidence was introduced as required by said Federal Food, Drug & Cosmetic Act.

(h) Because Respondent, Federal Security Administrator, established a definition and standard of identity for Enriched Farina, a new and hitherto unknown product composed of Farina and certain additional required ingredients, as well as certain optional ingredients, as appears from said Order, instead of establishing a definition and standard of identity for Farina which would permit the inclusion as an optional ingredient of Vitamin D, together with other optional ingredients, contrary to the intent, purposes and provisions of said Federal Food, Drug & Cosmetic Act.

(i) Because said Order will not promote honesty and fair dealing in the interests of consumers in accordance with the requirements of said Federal Food, Drug & Cosmetic Act.

(j) Because said Order does not fix and establish a reasonable definition and standard of identity for Farina as required by said Federal Food, Drug & Cosmetic Act.

(k) Because Respondent, Federal Security Administrator, has acted beyond his statutory power and authority.

(l) Because said Order violates the Fifth Amendment to the Constitution of the United States.

(m) Because the Act of Congress of June 25, 1938, (C. 675, Sec. 1; 52 Stat. 1040; 21 U. S. C. A. 301) known as the Federal Food, Drug & Cosmetic Act, is unconstitutional for the reason that it delegates unlawful authority to the Federal Security Administrator.

Prayer For Relief.

Wherefore, your Petitioner petitions for a review of said Order of Respondent, Federal Security Administrator, and respectfully prays:

1. That a certified copy of this Petition be forthwith served upon Respondent, Federal Security Adminstrator, according to law and the rules of this Court.

2. That said Respondent be required, in conformity to law, to certify to this Honorable Court a transcript of the Record in the proceedings wherein said Order was entered, including all Notices of Public Hearings, all proposed definitions and standards of identity, testimony of witnesses, exhibits, pleadings, findings, conclusions of law, all proposed Orders, and the Order of Respondent, Federal Security Administrator.

3. That pending final adjudication in this cause, this Honorable Court temporarily set aside said Order in whole in so far as it applies to Farina and Enriched Farina.

4. That said proceedings be reviewed by this Honorable Court and that Respondent, Federal Security Administrator, be ordered to amend said Order by finding that Vitamin D should be included as an optional ingredient in Farina, and by striking from said Order the definition and standard of identity for Enriched Farina, or, in the alternative, that said Order be in whole set aside, vacated and annulled in so far as it applies to Farina and Enriched Farina.

5. That this Honorable Court exercise its jurisdiction over the parties and subject matter of this Petition and grant Petitioner such other and further relief in the premises as the rights and equities require.

And you Petitioner will ever pray.

The Quaker Oats Company,
By John Stuart,
President.

Geo. J. Haight,
Ward Ross,
209 South LaSalle Street,
Chicago, Illinois,
Wm. D. McKenzie,
James M. Best,
1900-141 W. Jackson Boulevard,
Chicago, Illinois,
Attorneys for Petitioner.

United States of America,
State of Illinois,
County of Cook. } ss:

John Stuart, being first duly sworn, on oath deposes and says that he is the President of The Quaker Oats Company, a corporation, the Petitioner herein, and that he is duly authorized to make this affidavit; that he has read the above and foregoing and that the facts therein stated and set forth are true and correct.

John Stuart.

Subscribed and sworn to before me this 22nd day of August, 1941.

W. McKenzie Mothersill,
Notary Public.

(Seal)

EXHIBIT "A."

Title 21—Food and Drugs

Chapter I—Food and Drug Administration
(Docket No. FDC-21)

Part 15—Wheat Flour and Related Products; Definitions and Standards of Identity.

In the matter of a definition and standard of identity for each of the following foods: (A) Flour, White Flour, Wheat Flour, Plain Flour; (B) Enriched Flour; (C) Bromated Flour; (D) Enriched Bromated Flour; (E) Durum Flour; (F) Self-rising Flour, Self-Rising White Flour, Self-Rising Wheat Flour; (G) Enriched Self-rising Flour; (H) Phosphated Flour, Phosphated White Flour, Phosphated Wheat Flour; (I) Whole heat Flour, Graham Flour, Entire Wheat Flour; (J) Bromated Whole Wheat Flour; (K) Whole Durum Wheat Flour; (L) Crushed Wheat, Coarse Ground Wheat; (M) Cracked Wheat; (N) Farina; (O) Enriched Farina; (P) Semolina.

Final Order.

By virtue of authority vested in me by the provisions of the Federal Food, Drug, and Cosmetic Act, 52 Stat. 1046, 21 U.S.C. sec 341 (Supp. V, 1939); the Reorganization Act of 1939, 53 Stat. 561 ff., 5 U.S.C. sec. 133-133r (Supp. V, 1939); Reorganization Plans No. I (53 Stat. 1423, 4 F.R. 2727) and No. IV (5 F.R. 2421); upon the basis of evidence received at the hearings herein; and upon consideration of the exceptions filed against the proposed order issued by the Acting Federal Security Administrator on March 28, 1941 (6 F.R. 1729-1737), the following order is promulgated hereby:

Findings of Fact.

1. The food commonly and usually known as "flour," "white flour," "wheat flour," or "plain flour," is manufactured from wheat, both hard and soft, other than durum wheat and red durum wheat.

2. Flour is used primarily for making white bread and biscuit, and consumers of flour normally expect that it will be suitable for these purposes.

3. In making flour the wheat is first cleaned. It is usually tempered. It is then ground and bolted so as to separate the inner portion of the wheat berry, known as the endosperm, from the outer portions, known as the bran coat, or from both bran coat and germ. Flour consists essentially of finely ground endosperm. In the milling process the separation of bran coat and germ from endosperm is never complete, but a certain degree of separation is necessary to produce flour which will make acceptable white bread and biscuit.

4. Where all the flour milled from the wheat used is combined without separation into grades, the flour is called "straight flour." That portion which is most nearly free of bran coat and germ is frequently taken off and sold as "patent flour." The remaining portion, which contains more bran coat and germ than straight flour, is known as "clear flour."

5. "Straight flours" will make acceptable white bread and biscuit. As the degree of removal of bran coat and germ is lessened, flours become progressively less desirable for such purposes until so much bran coat and germ remain that acceptable white bread and biscuit cannot be made. However, such products are suitable for other food uses and are usually sold under such designations as "low-grade flour" and "second clear flour." Products containing even more bran coat and germ are sold usually as animal feed.

6. A reasonably accurate criterion of the degree of separation of bran coat, or bran coat and germ, from endosperm is the ash content of the flour, since the ash content of the bran coat is some 20 to 25 times that of the endosperm and the ash content of the germ some 10 to 15 times that of the endosperm.

7. In general, a limit on ash content can be used to distinguish between flours which will make acceptable white bread and biscuit and those which will not, but the limit is not the same for high protein flours (hard wheat flours) and low protein flours (soft wheat flours). In high protein flours, particularly those used for breadmaking, a somewhat lesser degree of separation is acceptable than in low protein flours.

8. In most straight flours the percent of ash is not more than one-twentieth of the percent of protein and is usually somewhat less.

9. Increased amounts of bran coat and germ which in-

crease the percent of ash to a point where it exceeds that of straight flour by more than 0.3 result in products which will not make acceptable white bread or biscuit. Products containing more ash than one-twentieth of the protein plus 0.3 percent are not generally sold in the household trade and are not generally used to make white bread or biscuit.

10. A maximum ash limit of one-twentieth of the protein plus 0.3 percent will distinguish reasonably effectively between flour suitable for making white bread and biscuits and products not suitable for those purposes.

11. Variation in the moisture content of flour after manufacture causes variations in the percent of protein and ash. The effect of such variations can be eliminated by calculating the percent of protein and ash to a moisture-free basis. When such calculation is made the figure 0.35 would be the approximate equivalent of, and should be substituted for, the figure 0.3 in Findings 9 and 10.

12. All flour contains some moisture. Excessive moisture, however, impairs the keeping quality of flour and unnecessarily increases its weight. A reasonable limit for moisture, which is not exceeded in good milling practice, is 15 percent.

13. Flour is a finely ground product and the degree of fineness is a distinguishing characteristic of flour. Such fineness is secured in good milling practice by bolting the flour through a cloth having openings not larger than those of woven wire cloth designated "149 micron (No. 100)" in table I of "Standard Specifications for Sieves", published March 1, 1940, in L. C. 584 of the U. S. Department of Commerce, National Bureau of Standards.

14. Malted wheat is sometimes mixed with wheat used for making flour, or malted wheat flour or malted barley flour is sometimes added to flour, in small amounts so as to compensate for natural deficiencies of enzymes necessary for breadmaking. A reasonable maximum limit for malted barley flour so added is 0.25 percent.

15. A satisfactory and reliable method for the determination of ash content of flour is that prescribed in the book "Official and Tentative Methods of Analysis of the Association of Official Agricultural Chemists", 4th edition, 1935, page 207, under the caption "Method I—Official." This method has recently been republished in the book "Official and Tentative Methods of Analysis of the Association of Official Agricultural Chemists", 5th edition, 1940, page

212, under the caption "Method I—Official." This method is well-known and widely used when examining flour for its ash content.

16. A satisfactory and reliable method for determination of moisture in flour is that prescribed in the book "Official and Tentative Methods of Analysis of the Association of Official Agricultural Chemists", 4th edition, 1935, page 206, under the caption "Vacuum Oven Method—Official." The same method has recently been republished in the book "Official and Tentative Methods of Analysis of the Association of Official Agricultural Chemists", 5th edition, 1940, page 211, under the caption "Vacuum Oven Method—Official." This method is well-known and widely used when examining flour for its moisture content.

17. The protein content of flour is ordinarily calculated from the nitrogen content of the flour by multiplying the nitrogen content by 5.7. A satisfactory and reliable chemical method for determination of nitrogen is that prescribed in the book "Official and Tentative Methods of Analysis of the Association of Official Agricultural Chemists", 4th edition, 1935, page 25, under the caption "Kjeldahl-Gunning-Arnold Method—Official." The same method has been recently republished in the book "Official and Tentative Methods of Analysis of the Association of Official Agricultural Chemists", 5th edition, 1940, page 26, under the caption "Kjeldahl-Gunning-Arnold Method—Official." This method is well-known and widely used for determining nitrogen in flour.

18. Flour as first prepared is slightly colored by the natural coloring in the wheat. It is a common practice in the milling industry to bleach the flour by treating it with one of more of the following bleaches or bleaching agents:

(1) Oxides of nitrogen.
(2) Chlorine.
(3) Nitrosyl chloride.
(4) Nitrogen trichloride.
(5) Benzoyl peroxide in a carrier consisting of either potassium alum and magnesium carbonate, or a mixture of calcium sulphate and magnesium carbonate, the weight of the carrier being in no case more than six times that of the benzoyl peroxide.

19. Besides the bleaching effect, chlorine, nitrosyl chloride, and nitrogen trichloride have an artificial aging effect on the flour so treated. Only enough of the bleaching

agent or agents to accomplish such desired effects is used. Excessive quantities impair the flour.

20. Flour so bleached is whiter than freshly milled unbleached flour, but is similar in color to unbleached flour naturally aged. Since about 1920 it has been prevailing trade practice to label flours treated with bleaching agents as "bleached." Many consumers have come to distinguish between bleached and unbleached flour, and are familiar with and understand the word "bleached" as applied to flour. The word "bleached", as so applied, has become the common name of the ingredients added to the flour through the bleaching process.

21. Some flour of high protein content, to which small amounts of potassium bromate have been added, can be made into dough which is easier to handle and which produces loaves of greater volume than dough made from the same flour to which no potassium bromate has been added. Addition of potassium bromate to flour has been practiced on a small scale, but the practice is increasing. Flour to which potassium bromate has been added is labeled "bromated" and sold exclusively to bakers. The name "bromated flour" is commonly and usually applied to differentiate this product from flour.

22. The amount of potassium bromate added depends on the properties of flour to which it is added, and varies in different crop years. The amount ordinarily used does not exceed 40 parts per million in domestic trade, or 75 parts per million in export trade. An excess of potassium bromate in dough has undesirable effects on bread. A reasonable minimum protein content of the flour used in making bromated flour is 13.5 percent, which is approximately equivalent to 15 percent when calculated to a moisture-free basis.

23. The food commonly and usually known as "self-rising flour", "self-rising white flour", or "self-rising wheat flour", is prepared by intimately mixing flour, a leavening agent, and salt for seasoning.

24. The leavening agent usually consists of a mixture of sodium bicarbonate and monocalcium phosphate. Sodium acid pyrophosphate, an acid salt of somewhat less neutralizing value than monocalcium phosphate, is sometimes substituted for monocalcium phosphate.

25. When self-rising flour is used in baking, carbon dioxide gas is evolved through the chemical reaction of the sodium bicarbonate and the acid leavening ingredient. The

gas so evolved leavens or raises the dough, giving the baked product one of its characteristic qualities. To accomplish this satisfactorily a certain minimum amount of carbon dioxide must be evolved. The amount of carbon dioxide gas which will be effective for the purpose of proper leavening is not less than 0.5 percent of the weight of the self-rising flour.

26. To avoid discoloration and other undesired characteristics in the baked product, the amounts of sodium bicarbonate and acid leavening ingredient must be so proportioned that no sodium bicarbonate remains unacted upon in the baked product. Unnecessarily large amounts of the leavening substances leave objectionable quantities of residues in the baked product. A reasonable maximum limit for the leavening agents in self-rising flour is four and one-half parts to each hundred parts of flour.

27. A satisfactory and reasonably accurate method for determining the amount of carbon dioxide evolved from self-rising flour is the method prescribed in "Official and Tentative Methods of Analysis of the Association of Official Agricultural Chemists", 5th edition, 1940, beginning on page 186 under "Gasometric Method with Chittick's Apparatus—Official", except that the following procedure is substituted for the procedure specified therein under "6—Determination":

Weigh 17 grams of the official sample into flask A, add 15-20 glass beads (4-6 mm. diameter) and connect this flask with the apparatus (fig. 22). Open stopcock C and by means of the leveling bulb E bring the displacement solution to the 25 cc. graduation above the zero mark. (This 25 cc. is a partial allowance for the volume of acid to be used in the decomposition). Allow the apparatus to stand 1-2 minutes to insure that the temperature and pressure within the apparatus are the same as those of the room. Close the stopcock, lower the leveling bulb somewhat to reduce the pressure within the apparatus, and slowly run into the decomposition flask from burette F 45 cc. of sulfuric acid (1+5). To prevent the liberated carbon dioxide from escaping through the acid burette into the air, keep the displacement solution in the leveling bulb at all times during the decomposition at a lower level than that in the gas-measuring tube. Rotate and then vigorously agitate the decomposition flask for three minutes to mix the contents intimately. Allow to stand for ten minutes to bring to equilibrium. Equalize the pressure in the

measuring tube by means of the leveling bulb and read the volume of gas from the zero point on the tube. Deduct 20 cc. from this reading (this 20 cc. together with previous allowance of 25 cc. compensates for the 45 cc. acid used in the decomposition). Observe the temperature of the air surrounding the apparatus and also the barometric pressure and multiply the number of cc. of gas evolved by the factor given in Table 24—Chapter XLIII for the temperature and pressure observed. Divide the corrected reading by 100 to obtain the apparent percent by weight of carbon dioxide in the official sample.

Correct the apparent percent of carbon dioxide to compensate for varying atmospheric conditions by immediately assaying a synthetic sample by the same method in the same apparatus.

Prepare the synthetic sample with 16.2 grams of flour, 0.30 gram of monocalcium phosphate, 0.30 gram of salt, and a sufficient quantity of sodium bicarbonate U. S. P. (dried over sulfuric acid) to yield the amount of carbon dioxide recovered in assay of official sample. Determine this quantity by multiplying weight of carbon dioxide recovered in assay of official sample by 1.91.

Divide the weight of carbon dioxide recovered from synthetic sample by weight of carbon dioxide contained in sodium bicarbonate used.

Divide the quotient into the apparent percent of carbon dioxide in official sample to obtain percent carbon dioxide evolved from the official sample.

28. There has recently been placed on the market a self-rising flour containing, in addition to the usual ingredients and in partial substitution for sodium bicarbonate, small amounts of calcium carbonate and light magnesium carbonate. Calcium carbonate and light magnesium carbonate react slowly with the acid ingredient when this self-rising flour is used in baking, but the reaction is incomplete and some calcium carbonate and light magnesium carbonate remain unchanged in the baked product. The method described in Finding 27 for determining the amount of carbon dioxide evolved is unsatisfactory where carbonates other than sodium bicarbonate are present in self-rising flour.

29. The reason for adding the calcium carbonate is to enrich the diet in calcium and to increase the ratio of calcium to phosphorus. The reason alleged for adding the light magnesium carbonate is that it tends to preserve in

the self-rising flour the fluffiness and free flowing qualities characteristic of freshly milled flour.

30. The probable effects of diversity of enrichment of self-rising flour, and of indiscriminate enrichment of foods, are set forth in Findings 36 and 37. In the amount used in this self-rising flour, 0.176 percent, and in amounts up to 0.5 percent light magnesium carbonate causes no observable change in fluffiness, free flowing qualities, or other properties of the self-rising flour.

31. The flour used in preparing self-rising flour is ordinarily bleached prior to mixing with leavening agents and salt. Sometimes the bleaching agent containing benzoyl peroxide, described in Finding 18, is mixed with the flour along with the leavening agents and salt. Findings 18, 19, and 20 apply also to self-rising flour.

32. Flour and self-rising flour are among the principal items of food of the people of the United States. The average consumption is about six and one-half ounces per person per day. This six and one-half ounces supplies about one-fourth of the normal energy requirements of the average person.

33. Recent investigations of the diets of persons in various sections and in various income groups have shown that in many cases the food consumed does not furnish sufficient amounts of certain necessary nutritional elements to maintain health. These deficiencies are more prevalent in the case of persons with low incomes. Such persons usually supply a larger part of their energy requirements from flour and self-rising flour than the average person because of their cheapness as a source of energy.

34. Among the most serious and widespread deficiencies in children as well as adults, are those of vitamin B_1, riboflavin, nicotinic acid, and iron. Deficiencies of these vitamins tend to occur in the same individuals.

35. A deficiency of calcium exists in certain groups of the population. A deficiency of vitamin D exists in large numbers of infants and children.

36. There have recently been placed on the market flours and self-rising flours enriched with one or more of the nutritional elements referred to above. These flours vary widely in composition. Unless a standard is promulgated which limits the kinds and amounts of enrichment, the manufacturers' selection of the various nutritive elements and combinations of elements on the basis of economic and merchandising considerations is likely to lead

to a great increase in the diversity, both qualitative and quantitative, in enriched flours offered to the public. Such diversity would tend to confuse and mislead consumers as to the relative value of and need for the several nutritional elements, and would impede rather than promote honesty and fair dealing in the interest of consumers.

37. In general, indiscriminate enrichment of foods (including flour and self-rising flour) with vitamins and minerals would tend to confuse and mislead consumers by giving rise to conflicting claims regarding the beneficial effects of such substances, and would be likely to lead to the impression on the part of consumers that a single article of food so enriched would meet all nutritional needs.

38. Limited enrichment of selected staple foods, on the other hand, is readily adapted to the promotion of consumer understanding of the relative value of enriched and natural foods, utilizing such education as consumers have received regarding the nutritive value of natural foods.

39. Essential food elements, now present only in insufficient quantities in many diets, which are present in wheat in considerable quantity, are vitamins of the B complex and iron. Iron (or compounds of iron) and the following vitamins of the B complex are available and suitable for the enrichment of flour and self-rising flour, either in the form of synthetic products or secured from wheat by slight changes in the process of milling flour: vitamin B_1, riboflavin, nicotinic acid or nicotinic acid amide.

40. Vitamin D and calcium are now used singly to a limited extent in the enrichment of flour and self-rising flour. Consumer education has generally recommended dairy products as the most desirable source of calcium, and milk as the product most suitable for enrichment with vitamin D in the light of known deficiencies of this element. The addition, however, of vitamin D and calcium as optional ingredients to an enriched flour or enriched self-rising flour will serve a useful purpose for the benefit of persons who do not consume sufficient dairy products.

41. Enrichment of flour or self-rising flour with vitamin A or vitamin C would be unsatisfactory for the reason, among others, that these vitamins are likely to decompose in flour.

42. Stabilized wheat germ oil has been proposed as an optional ingredient of flour for the purpose of increasing the vitamin E content of the flour and for its flavor. The need for the enrichment of foods with vitamin E has not

been established. The evidence does not establish that wheat germ oil or stabilized wheat germ oil, in the quantity proposed, has an appreciable effect on the flavor.

43. Pending experience with the use of enriched flour and enriched self-rising flour, consumer education and understanding will be facilitated by restricting the enrichment, not only with respect to the ingredients to be contained therein, but also by the fixing of minimum and maximum amounts of such ingredients. Reasonable limits for this purpose are, for each pound of flour or self-rising flour: not less than 1.66 milligrams nor more than 2.5 milligrams of vitamin B_1, not less than 1.2 milligrams nor more than 1.8 milligrams of riboflavin, not less than 6 milligrams nor more than 24 milligrams of nicotinic acid or nicotinic acid amide, not less than 6 milligrams nor more than 24 milligrams of iron (Fe), not less than 250 U. S. P. units nor more than 1,000 U. S. P. units of vitamin D, and not less than 500 milligrams nor more than 2,000 milligrams of calcium (Ca).

44. Wheat germ, in its natural form or processed to remove part of its oil, is a suitable ingredient for furnishing a part of the requirements for vitamin B_1, riboflavin, nicotinic acid, and iron, but amounts greater than 5 percent in flour or self-rising flour impair the color of the baked product and make it difficult to produce acceptable bread.

45. Iron has been added to flour in the form of harmless and assimilable salts (other harmless and assimilable forms of iron would serve as well). Various harmless and assimilable salts of calcium, including the phosphates, have been used. The use of any of the calcium phosphates results in the introduction of phosphorus in addition to that naturally present in flour, but such introduction is harmless and is thought by some persons to be desirable. Vitamin D has been added to flour as a concentrate of vitamin D in a food oil. When vitamins and iron are added to flour or self-rising flour, their bulk is so small that the use of a carrier facilitates their intimate and uniform admixture with the flour.

46. Vitamin B_1 in flour and self-rising flour is subject to some loss during baking; the degree of loss increases as the dough decreases in acidity or becomes alkaline. The danger of loss is great when consumers use soda in baking. The addition of monocalcium phosphate safeguards against such losses.

47. Flour and self-rising flour enriched with vitamins

and minerals have not acquired common or usual names; accurate designations for these products are "enriched flour" and "enriched self-rising flour."

48. The reasons for enriching flour with vitamins and minerals are equally applicable to bromated flour. Bromated flour so enriched has not acquired a common or usual name; an accurate designation for this product is "enriched bromated flour."

49. The food commonly and usually known as "durum flour" is manufactured from durum wheat. Durum flour is not ordinarily used for making bread or biscuit but is used for making macaroni and noodles. The purchaser of durum flour expects that it will be suitable for these purposes.

50. Except as above stated, the method of preparation of durum flour is the same as that described in Finding 3 with respect to flour. Finding 6 is applicable to durum flour.

51. The characteristics of durum wheat do not vary to an extent comparable to the variation between hard and soft wheats used for making flour, and a fixed ash limit is satisfactory for distinguishing between durum flours which will make acceptable macaroni and noodles and those which will not. A reasonable ash limit is 1.3 percent, or 1.5 percent when calculated to a moisture-free basis.

52. Findings 12, 13, 15, and 16 are applicable to durum flour.

53. A food is prepared and widely sold in certain parts of the United States consisting of a mixture of flour and monocalcium phosphate, sometimes with the addition of dicalcium phosphate.

54. The primary reason for adding the monocalcium phosphate is to have an excess of acid-reacting material in the dough when such flour is used with soda and sour milk for making biscuit. Dicalcium phosphate also increases the acid-reacting material, but it is far less effective for this purpose than monocalcium phosphate, and the primary reason for adding it is to enrich the diet in calcium. The probable effects of diversity of enrichment of flour, and of indiscriminate enrichment of foods, are set forth in Findings 36 and 37.

55. Small amounts of monocalcium phosphate will not accomplish the purpose of such addition; too much is likely to impart an undesirable acid taste to products made from such flour. Reasonable limits for monocalcium phosphate

are a minimum of 0.25 percent and a maximum of 0.75 percent of the weight of the phosphated flour.

56. Flour to which monocalcium phosphate has been added is commonly labeled "flour—calcium phosphate added." The names "phosphated flour", "phosphated white flour", and "phosphated wheat flour" are commonly and usually applied to differentiate this product from flour.

57. The flour used in preparing phosphated flour is ordinarily bleached prior to mixing with the monocalcium phosphate. Sometimes the bleaching agent containing benzoyl peroxide, described in Finding 18, is mixed with the flour along with the monocalcium phosphate. Findings 18, 19 and 20 apply also to phosphated flour.

58. The three foods commonly and usually known as (1) "whole wheat flour", "graham flour", or "entire wheat flour"; (2) "cracked wheat"; (3) "crushed wheat" or "coarse ground wheat", are all made by grinding, cracking, or crushing wheat other than durum wheat or red durum wheat. Consumers generally expect these foods to contain the constituents of the whole wheat berry, other than moisture, in their natural proportions, although in some cases some of the finer material (largely endosperm and germ) or the coarser material (largely bran) is removed, the product often being labeled to show such removal.

59. In the manufacture of these foods the wheat is first cleaned, and is sometimes tempered. Each of these foods contains some moisture. Excessive moisture, however, impairs the keeping qualities and unreasonably increases the weight of these foods. A reasonable limit for moisture, which is not exceeded in good manufacturing practice, is 15 percent.

60. Food products made from the entire wheat berry vary widely in the size of particles. They also vary in the character and shape of the particles, depending on whether the products are made by a grinding or crushing process or by a cracking or cutting process. A ground or crushed product, even though coarsely ground, contains a substantial amount of fine particles. A cracked or cut product, although it may contain some fine particles, consists chiefly of angular fragments of substantially uniform size.

61. The most finely ground of these products is commonly and usually known as "whole wheat flour", "graham flour", or "entire wheat flour." This product is commonly

used for making whole wheat bread, and the purchaser expects it to be suitable for that purpose.

62. In order to make whole wheat bread, whole wheat flour must be of a certain degree of fineness. Reasonable limits for the degree of fineness for this purpose are that at least 90 percent of the whole wheat flour pass through a No. 8 sieve and at least 50 percent of it pass through a No. 20 sieve. Most, though not all, products now sold under the name "whole wheat flour" comply with such limitations.

63. Malted wheat is sometimes mixed with wheat used for making whole wheat flour, or malted wheat flour or malted barley flour is sometimes added to the whole wheat flour, in small amounts so as to compensate for natural deficiencies of enzymes necessary for breadmaking. A reasonable maximum limit for malted wheat flour so used is 0.5 percent, and for malted barley flour so used is 0.25 percent.

64. In the process of milling whole wheat flour, the particles of endosperm sometimes are separated from the ground particles of bran coat and germ of the wheat, and subsequently recombined. In such cases the particles of endosperm are sometimes treated with nitrogen trichloride, chlorine, or a mixture of nitrozyl chloride and chlorine to obtain bleaching and artificial aging effects. Only enough of these agents is used to bring about these effects. Whole wheat flour so treated is labeled "bleached."

65. Products coarser than whole wheat flour, while not suitable for use as the primary ingredient in making bread, are used with flour or whole wheat flour to make special kinds of bread, often designated "cracked wheat bread" and "crushed wheat bread." They are also used to some extent as breakfast foods or an ingredient of certain breakfast foods. In order to be suitable for these purposes the products must be of a certain degree of fineness.

66. Products made by the cracking or cutting process have a different appearance and different texture from those made by the grinding or crushing process. But considerable confusion now exists in regard to nomenclature of these products, with the result that purchasers of them or of bread containing them are likely to have difficulty in knowing what they are purchasing. Thus, the name "cracked wheat", while it is generally applied to products made by the cracking or cutting process, is also applied occasionally to coarsely ground food products of wheat.

The name "cracked wheat" is also applied to animal feed which differs in several respects from products sold for human food, being made up mostly of broken or cracked wheat berries. The fineness of these food products is important in determining their suitability for the purposes stated in Finding 65, and the degree of fineness and of uniformity in the size of particles affords a reasonable method (in addition to the difference in the method of manufacture and in shape and character of particles) of differentiating between them.

67. The coarse product made by the grinding process or crushing process is usually sold under the name "crushed wheat", and sometimes as "rolled wheat", or "curled wheat", and occasionally as "cracked wheat." The term "coarse ground wheat" has also been proposed. Reasonable limits on the sizes of the particles of this product, which is suitable for the purposes stated in Findings 65, are that at least 40 percent will pass through a No. 8 sieve, but less than 50 percent will pass through a No. 20 sieve.

68. The coarse product made by the cracking or cutting process is commonly known as "cracked wheat." Reasonable limits on the size of the particles of this product, which is suitable for the purposes stated in Finding 65, are that at least 90 percent will pass through a No. 8 sieve and not more than 20 percent will pass through a No. 20 sieve.

69. A suitable procedure for determining the percentage of these foods which will be retained on or pass through No. 8 and No. 20 sieves is as follows:

Use No. 8 and No. 20 sieves, having standard 8-inch full height frames, complying with the specifications for wire cloth and sieve frames in "Standard Specifications for Sieves," published March 1, 1940, in L. C. 584 of the U. S. Department of Commerce, National Bureau of Standards. Fit a No. 8 sieve into a No. 20 sieve. Attach bottom pan to the No. 20 sieve. Pour 100 grams of the sample into the No. 8 sieve. Attach cover and hold the assembly in a slightly inclined position with one hand. Shake the sieves by striking the sides against the other hand with an upward stroke, at the rate of about 150 times per minute. Turn the sieves about one-sixth of a revolution, each time in the same direction, after each 25 strokes. Continue shaking for two minutes. Weigh the material which fails to pass through the No. 8 sieve and the material which passes through the No. 20 sieve.

70. A satisfactory and reliable method for the deter-

mination of moisture in whole wheat flour is that referred to in Finding 16. This method is well-known and widely used in examining whole wheat flour for its moisture content.

71. A satisfactory and reliable method for the determination of moisture in cracked wheat and crushed wheat is that prescribed in the book "Official and Tentative Methods of Analysis of the Association of Official Agricultural Chemists," 4th Edition, 1935, page 335, under the caption "Preparation of Sample—Official" and "Moisture I. Drying with Heat—Official." The same method has recently been republished in the book "Official and Tentative Methods of Analysis of the Association of Official Agricultural Chemists," 5th edition, 1940, page 353, under "Preparation of Sample—Official" and "Moisture I. Drying with Heat—Official." This method is well-known and widely used in examining crushed wheat and cracked wheat for their moisture content.

72. The reasons for adding potassium bromate to flour, and the amounts in which it is added, stated in Findings 21 and 22, are equally applicable to whole wheat flour. Whole wheat flour to which potassium bromate is added is labeled "bromated"; an accurate designation for the product is "bromated whole wheat flour."

73. The food known as "whole durum wheat flour" is prepared from durum wheat by the same process employed in making whole wheat flour (Findings 59, 62, 63, 64, and 65), and is used in making certain kinds of bread. Consumers generally expect whole durum wheat flour to contain the constituents of the whole durum wheat berry, other than moisture, in their natural proportions. A reasonable moisture limit and reasonable granulation limits for whole durum wheat flour are the same as for whole wheat flour.

74. The food commonly and usually known as "farina" is manufactured from wheat, either hard or soft, other than durum wheat and red durum wheat.

75. In making farina the wheat is first cleaned. It is usually tempered. It is then ground, bran coat and germ are separated from the endosperm, and the flour is removed by bolting. Farina consists essentially of endosperm, but the particles of farina are larger than those of flour. The size of the particles of farina has become well established through usage, and is a distinguishing characteristic of the product. The size is such that farina will pass through a No. 20 sieve but that only a small amount will pass through

a No. 100 sieve. The material passing through the No. 100 sieve comes mostly from abrasion of particles of farina during handling after it is manufactured. A reasonable limit for this fine material is 3.0 percent.

76. A satisfactory method for testing farina for size of particles is as follows:

Use No. 20 and No. 100 sieves, having standard 8-inch full height frames, complying with the specifications for wire cloth and sieve frames in "Standard Specifications for Sieves", published March 1, 1940, in L. C. 584 of the U. S. Department of Commerce, National Bureau of Standards. Fit a No. 20 sieve into a No. 100 sieve. Attach bottom pan to the No. 100 sieve. Four 100 grams of the sample into the No. 20 sieve. Attach cover and hold the assembly in a slightly inclined position with one hand. Shake the sieves by striking the sides against the other hand with an upward stroke, at the rate of about 150 times per minute. Turn the sieves about one-sixth of a revolution, each time in the same direction, after each 25 strokes. Continue shaking for two minutes. Weigh the material which fails to pass through the No. 20 sieve and the material which passes through the No. 100 sieve.

77. Consumers generally expect farina to be almost entirely free from bran coat and germ. In this respect it corresponds substantially to "patent flour." The extent of removal can be measured by the percent of ash in the farina (see Finding 6). A generally recognized and reasonable maximum limit for ash is about 0.6 percent, or not more than 0.6 percent on a moisture-free basis.

78. All farina contains some moisture. Excessive moisture impairs the keeping qualities of farina and unnecessarily increases its weight. A reasonable limit for moisture, which is not exceeded in good milling practice, is 15 percent.

79. A satisfactory and reliable method for the determination of the ash content of farina is that referred to in Finding 15. A satisfactory and reliable method for the determination of the moisture content of farina is that referred to in Finding 16. These methods are well-known and widely used.

80. The removal of bran coat and germ from endosperm in the manufacture of farina removes those parts of the wheat which are richest in vitamins and minerals.

81. Farina is used as a breakfast food and as an ingredient of macaroni products. It is not as widely con-

sumed as flour, but it is extensively used as a cereal food for children and in many cases is the only cereal food used during a period of their growth.

82. Certain manufacturers are now selling farina to which have been added vitamins and minerals. Ingredients now being added for this purpose are vitamin D contained in dried irradiated yeast (other sources of vitamin D would serve equally well), and portions of the vitamin B complex and minerals contained in freshly milled wheat germ or wheat germ from which part of the oil has been removed. Iron and calcium have also been added in the form of assimilable salts, which are available and suitable for the purpose. In addition to wheat germ other sources of members of the vitamin B complex are available and suitable.

83. In general, the interest of consumers is affected by the enrichment of farina with vitamins and minerals in the same way as has been outlined in connection with the enrichment of flour in Findings 34 to 43, inclusive.

84. Because of the small quantities in which farina is ordinarily consumed, and because of its special use in diets of some children, there is occasion for the enrichment of farina with quantities of vitamins and minerals substantially in excess of the reasonable maxima for flour. Findings 44 and 45 are applicable to farina, except that farina is not used for making bread and a reasonable limit for the wheat germ is 8 percent.

85. The time necessary for cooking enriched farina can be shortened by the addition of from one-half to one percent of disodium phosphate.

86. Farina enriched with vitamins and minerals has not acquired a common or usual name; an accurate designation for the product is "enriched farina."

87. The food commonly and usually known as semolina is manufactured from durum wheat.

88. In making semolina the wheat is first cleaned. It is usually tempered. It is then ground, the bran coat and germ are separated from the endosperm, and durum flour is removed by bolting. Semolina consists essentially of the endosperm, but the particles of semolina are larger than those of durum flour. The size of the particles of semolina has become well established through usage, and is a distinguishing characteristic of the product. The size is such that semolina will pass through a No. 20 sieve but that only a small amount will pass through a No. 100 sieve. The material passing through the No. 100 sieve comes

mostly from abrasion of particles of semolina during handling after it is manufactured. A reasonable limit for this fine material is 3.0 percent.

89. A satisfactory method for testing semolina for size of particles is the method described in Finding 76.

90. Semolina is used in the manufacture of macaroni and noodles, and sometimes as a breakfast food. Consumers generally expect semolina to be almost entirely free from bran coat and germ. The extent of the removal can be measured by the percent of ash in the semolina (see Finding 6). A generally recognized and reasonable limit for ash is about 0.8 percent or not more than 0.92 percent on a moisture-free basis.

91. All semolina contains some moisture. Excessive moisture impairs the keeping qualities of semolina and unnecessarily increases its weight. A reasonable limit for moisture, which is not exceeded in good manufacturing practice, is 15 percent.

92. A satisfactory and reliable method for the determination of the ash content of semolina is that referred to in Finding 15. A satisfactory and reliable method for determination of the moisture content of semolina is that referred to in Finding 16. These methods are well-known and widely used.

On the basis of the foregoing findings of fact it is concluded that each of the following regulations fixing and establishing a definition and standard of identity for a food will promote honesty and fair dealing in the interest of consumers:

Regulations.

§ 15.000 Flour, white flour, wheat flour, plain flour—identity; label statement of optional ingredients. (a) Flour, white flour, wheat flour, plain flour, is the food prepared by grinding and bolting cleaned wheat other than durum wheat and red durum wheat; to compensate for any natural deficiency of enzymes, malted wheat, malted wheat flour, malted barley flour, or any combination of two or more of these, may be used; but the quantity of malted barley flour so used is not more than 0.25 percent. One of the cloths through which the flour is bolted has openings not larger than those of woven wire cloth designated "149 micron (No. 100)" in table I of "Standard Specifications for Sieves", published March 1, 1940, in L. C. 584 of the U. S. Department of Commerce, National Bureau of

Standards. The flour is freed from bran coat, or bran coat and germ, to such extent that the percent of ash therein, calculated to a moisture-free basis, is not more than the sum of one-twentieth of the percent of protein therein, calculated to a moisture-free basis, and 0.35. Its moisture content is not more than 15 percent. Unless such addition conceals damage or inferiority of the flour or makes it appear better or of greater value than it is, one or any combination of two or more of the following optional bleaching ingredients may be added in a quantity not more than sufficient for bleaching or, in case such ingredient has an artificial aging effect, in a quantity not more than sufficient for bleaching and such artificial aging effect:

(1) oxides of nitrogen,
(2) chlorine,
(3) nitrosyl chloride,
(4) nitrogen trichloride,
(5) one part by weight of benzoyl peroxide mixed with not more than six parts by weight of a mixture of either potassium alum or calcium sulfate and magnesium carbonate.

(b) When any optional bleaching ingredient is used, the label shall bear the word "Bleached." Wherever the name of the food appears on the label so conspicuously as to be easily seen under customary conditions of purchase, the word "Bleached" shall immediately and conspicuously precede or follow such name, without intervening written, printed, or graphic matter; except that where such name is a part of a trade-mark or brand, other written, printed, or graphic matter, which is also a part of such trade-mark or brand, may so intervene if the word "Bleached" is in such juxtaposition with such trade-mark or brand as to be conspicuously related to such name.

(c) For the purposes of this section:

(1) Ash is determined by the method prescribed in the book "Official and Tentative Methods of Analysis of the Association of Official Agricultural Chemists", 5th edition, 1940, page 212, under "Method I—Official." Ash is calculated to a moisture-free basis by subtracting the percent of moisture in the flour from 100, dividing the remainder into the percent of ash, and multiplying the quotient by 100.

(2) Protein is 5.7 times the nitrogen as determined by the method prescribed in such book on page 26, under "Kjeldahl-Gunning-Arnold Method—Official." Protein is calculated to a moisture-free basis by subtracting the per-

cent of moisture in the flour from 100, dividing the remainder into the percent of protein, and multiplying the quotient by 100.

(3) Moisture is determined by the method prescribed in such book on page 211, under "Vacuum Oven Method—Official."*

§ 15.010 Enriched flour—identity; label statement of optional ingredients. Enriched flour conforms to the definition and standard of identity, and is subject to the requirements for label statement of optional ingredients, prescribed for flour by § 15.000, except that:

(a) it contains in each pound not less than 1.66 milligrams and not more than 2.5 milligrams of vitamin B_1, not less than 1.2 milligrams and not more than 1.8 milligrams of riboflavin, not less than 6 milligrams and not more than 24 milligrams of nicotinic acid or nicotinic acid amide, not less than 6 milligrams and not more than 24 milligrams of iron (Fe);

(b) vitamin D may be added in such quantity that each pound of the finished enriched flour contains not less than 250 U. S. P. units and not more than 1,000 U. S. P. units of vitamin D;

(c) calcium may be added in such quantity that each pound of the finished enriched flour contains not less than 500 milligrams and not more than 2,000 milligrams of calcium (Ca), except that enriched flour may be acidified with monocalcium phosphate irrespective of the minimum limit for calcium (Ca) herein prescribed;

(d) it may contain not more than 5 percent by weight of wheat germ or partly defatted wheat germ; and

(e) in determining whether the ash content complies with the requirements of this section allowance is made for ash resulting from any added iron or salts of iron or calcium.

Iron and calcium may be added only in forms which are harmless and assimilable. The substances referred to in paragraphs (a) and (b) may be added in a harmless carrier which does not impair the enriched flour; such carrier is used only in the quantity necessary to effect an intimate and uniform admixture of such substances with the flour.

§ 15.020 Bromated flour—identity; label statement of optional ingredients. Bromated flour conforms to the

* §§ 15.000 to 15.150, inclusive, issued under the authority contained in 52 Stat. 1046, 53 Stat. 1061ff; 21 U. S. C., Sup. 341, 5 U. S. C., Sup. 133-133t and Reorganization Plans Nos. I and IV, 4 F. R. 2727, 5 F. R. 2421.

definition and standard of identity, and is subject to the requirements for label statement of optional ingredients, prescribed for flour by § 15.000, except that:

(a) potassium bromate is added in a quantity not exceeding 75 parts to each million parts of the finished bromated flour; and

(b) its protein content, calculated to a moisture-free basis, is not less than 15 percent (determination and calculations of protein are made as prescribed in § 15.000 (c) (2)).

§ 15.030 Enriched bromated flour—identity; label statement of optional ingredients. Enriched bromated flour conforms to the definition and standard of identity, and is subject to the requirements for label statement of optional ingredients, prescribed for enriched flour by § 15.010, except that:

(a) potassium bromate is added in a quantity not exceeding 75 parts to each million parts of the finished enriched bromated flour; and

(b) its protein content, calculated to a moisture-free basis, is not less than 15 percent (determination and calculations of protein are made as prescribed in § 15.000 (c) (2)).

§ 15.040 Durum flour—identity. (a) Durum flour is the food prepared by grinding and bolting cleaned durum wheat. One of the cloths through which such flour is bolted has openings not larger than those of woven wire cloth designated "149 micron (No. 100)" in table I of "Standard Specifications for Sieves", published March 1, 1940, in L. C. 584 of the U. S. Department of Commerce, National Bureau of Standards. It is freed from bran coat, or bran coat and germ, to such extent that the percent of ash therein, calculated to a moisture-free basis, is not more than 1.5 percent. Its moisture content is not more than 15 percent.

(b) For the purposes of this section, ash and moisture are determined by the methods therefor referred to in § 15.000 (c).

§ 15.050 Self-rising flour, self-rising white flour, self-rising wheat flour—identity; label statement of optional ingredients. (a) Self-rising flour, self-rising white flour, self-rising wheat flour, is an intimate mixture of flour, sodium bicarbonate, and the acid-reacting substance monocalcium phosphate or sodium acid pyrophosphate or both. It is seasoned with salt. When it is tested by the method prescribed in subsection (c), not less than 0.5 percent of

carbon dioxide is evolved. The acid-reacting substance is added in sufficient quantity to neutralize the sodium bicarbonate. The combined weight of such acid-reacting substance and sodium bicarbonate is not more than 4.5 parts to each 100 parts of flour used. Subject to the conditions and restrictions prescribed by § 15.000 (a), the bleaching ingredients specified in such section may be added as optional ingredients. If the flour used in making the self-rising flour is bleached, the optional bleaching ingredient used therein (see § 15.000 (a)) is also an optional ingredient of the self-rising flour.

(b) When any optional bleaching ingredient is used, the label shall bear the word "Bleached." Wherever the name of the food appears on the label so conspicuously as to be easily seen under customary conditions of purchase, the word "Bleached" shall immediately and conspicuously precede or follow such name, without intervening written, printed, or graphic matter; except that where such name is a part of a trade-mark or brand, other written, printed, or graphic matter, which is also a part of such trade-mark or brand, may so intervene if the word "Bleached" is in such juxtaposition with such trade-mark or brand as to be conspicuously related to such name.

(c) The method referred to in paragraph (a) is the method prescribed in "Official and Tentative Methods of Analysis of the Association of Official Agricultural Chemists", 5th edition, 1940, beginning on page 186 under "Gasometric Method with Chittick's Apparatus—Official", except that the following procedure is substituted for the procedure specified therein under "6—Determination".

Weigh 17 grams of the official sample into flask A, add 15-20 glass beads (4-6 mm. diameter), and connect this flask with the apparatus (fig. 22). Open stopcock C and by means of the leveling bulb E bring the displacement solution to the 25 cc. graduation above the zero mark. (This 25 cc. is a partial allowance for the volume of acid to be used in the decomposition.) Allow the apparatus to stand 1-2 minutes to insure that the temperature and pressure within the apparatus are the same as those of the room. Close the stopcock, lower the leveling bulb somewhat to reduce the pressure within the apparatus, and slowly run into the decomposition flask from burette F 45 cc. of sulfuric acid (1+3). To prevent the liberated carbon dioxide from escaping through the acid burette into the air, keep the displacement solution in the leveling bulb at all times during

the decomposition at a lower level than that in the gas-measuring tube. Rotate and then vigorously agitate the decomposition flask for three minutes to mix the contents intimately. Allow to stand for ten minutes to bring to equilibrium. Equalize the pressure in the measuring tube by means of the leveling bulb and read the volume of gas from the zero point on the tube. Deduct 20 cc. from this reading (this 20 cc. together with previous allowance of 25 cc. compensates for the 45 cc. acid used in the decomposition). Observe the temperature of the air surrounding the apparatus and also the barometric pressure and multiply the number of cc. of gas evolved by the factor given in table 24—Chapter XLIII for the temperature and pressure observed. Divide the corrected reading by 100 to obtain the apparent percent by weight of carbon dioxide in the official sample.

Correct the apparent percent of carbon dioxide to compensate for varying atmospheric conditions by immediately assaying a synthetic sample by the same method in the same apparatus.

Prepare the synthetic sample with 16.2 grams of flour, 0.30 gram of monocalcium phosphate, 0.30 gram of salt, and a sufficient quantity of sodium bicarbonate U. S. P. (dried over sulfuric acid) to yield the amount of carbon dioxide recovered in assay of official sample. Determine this quantity by multiplying weight of carbon dioxide recovered in assay of official sample by 1.91.

Divide the weight of carbon dioxide recovered from synthetic sample by weight of carbon dioxide contained in sodium bicarbonate used.

Divide the quotient into the apparent percent of carbon dioxide in official sample to obtain percent of carbon dioxide evolved from the official sample."

§ 15.060 Enriched self-rising flour—identity; label statement of optional ingredients. Enriched self-rising flour conforms to the definition and standard of identity, and is subject to the requirements for label statement of optional ingredients, prescribed for self-rising flour by § 15.050, except that:

(a) it contains in each pound not less than 1.66 milligrams and not more than 2.5 milligrams of vitamin B_1, not less than 1.2 milligrams and not more than 1.8 milligrams of riboflavin, not less than 6 milligrams and not more than 24 milligrams of nicotinic acid or nicotinic acid amide, not

less than 6 milligrams and not more than 24 milligrams of iron (Fe);

(b) vitamin D may be added in such quantity that each pound of the finished enriched self-rising flour contains not less than 250 U. S. P. units and not more than 1,000 U. S. P. units of vitamin D;

(c) calcium may be added in such quantity that each pound of the finished enriched self-rising flour contains not less than 500 milligrams and not more than 2,000 milligrams of calcium (Ca);

(d) it may contain not more than 5 percent by weight of wheat germ or partly defatted wheat germ;

(e) when calcium is added as dicalcium phosphate, such dicalcium phosphate is also considered to be an acid-reacting substance; and

(f) when calcium is added as carbonate, the method set forth in § 15.040 (c) does not apply as a test for carbon dioxide evolved; but in such case the quantity of carbon dioxide evolved under ordinary conditions of use of the enriched self-rising flour is not less than 0.5 percent of the weight thereof.

Iron and calcium may be added only in forms which are harmless and assimilable. The substances referred to in paragraphs (a) and (b) may be added in a harmless carrier which does not impair the enriched self-rising flour; such carrier is used only in the quantity necessary to effect an intimate and uniform admixture of such substances with the flour.

§ 15.070 Phosphated flour, phosphated white flour, phosphated wheat flour—identity; label statement of optional ingredients. Phosphated flour, phosphated white flour, phosphated wheat flour, conforms to the definition and standard of identity, and is subject to the requirements for label declaration of optional ingredients, prescribed for flour by § 15.000, except that:

(a) monocalcium phosphate is added in a quantity not less than 0.25 percent and not more than 0.75 percent of the weight of the finished phosphated flour; and

(b) in determining whether the ash content complies with the requirements of this regulation allowance is made for the added monocalcium phosphate.

§ 15.080 Whole wheat flour, graham flour, entire wheat flour—identity; label statement of optional ingredients. (a) Whole wheat flour, graham flour, entire wheat flour is the food prepared by so grinding cleaned wheat other than

durum wheat and red durum wheat that, when tested by the method prescribed in subsection (c) (2), not less than 90 percent passes through a No. 8 sieve and not less than 50 percent passes through a No. 20 sieve. The proportions of the natural constituents of such wheat, other than moisture, remain unaltered. To compensate for any natural deficiency of enzymes, malted wheat, malted wheat flour, malted barley flour, or any combination of two or more of these, may be used; but the quantity of malted wheat flour so used is not more than 0.5 percent, and the quantity of malted barley flour so used is not more than 0.25 percent. The moisture content of whole wheat flour is not more than 15 per cent. Unless such addition conceals damage or inferiority of the whole wheat flour or makes it appear better or of greater value than it is, the optional bleaching ingredient nitrogen trichloride, chlorine, or a mixture of nitrosyl chloride and chlorine, may be added in a quantity not more than sufficient for bleaching and artificial aging effects.

(b) When any optional bleaching ingredient is used, the label shall bear the word "Bleached." Wherever the name of the food appears on the label so conspicuously as to be easily seen under customary conditions of purchase, the word "Bleached" shall immediately and conspicuously precede or follow such name, without intervening written, printed, or graphic matter; except that where such name is a part of a trade-mark or brand, other written, printed, or graphic matter, which is also a part of such trade-mark or brand, may so intervene if the word "Bleached" is in such juxtaposition with such trade-mark or brand as to be conspicuously related to such name.

(c) For the purpose of this section:

(1) Moisture is determined by the method prescribed in "Official and Tentative Methods of Analysis of the Association of Official Agricultural Chemists", 5th edition, 1940, page 211, under "Vacuum Oven Method—Official."

(2) The method referred to in paragraph (a) is as follows: Use No. 8 and No. 20 sieves, having standard 8-inch full height frames, complying with the specifications for wire cloth and sieve frames in "Standard Specifications for Sieves", published March 1, 1940, in L. C. 584 of the U. S. Department of Commerce, National Bureau of Standards. Fit a No. 8 sieve into a No. 20 sieve. Attach bottom pan to the No. 20 sieve. Pour 100 grams of the sample into the No. 8 sieve. Attach cover and hold the assembly

in a slightly inclined position with one hand. Shake the sieves by striking the sides against the other hand with an upward stroke, at the rate of about 150 times per minute. Turn the sieves about one-sixth of a revolution, each time in the same direction, after each 25 strokes. Continue shaking for two minutes. Weigh the material which fails to pass through the No. 8 sieve and the material which passes through the No. 20 sieve.*

§ 15.090 Bromated whole wheat flour—identity; label statement of optional ingredients. Bromated whole wheat flour conforms to the definition and standard of identity, and is subject to the requirements for label statement of optional ingredients, prescribed for whole wheat flour by § 15.080, except that potassium bromate is added in a quantity not exceeding 75 parts to each million parts of finished bromated whole wheat flour.*

§ 15.100 Whole durum wheat flour—identity; label statement of optional ingredients. Whole durum wheat flour conforms to the definition and standard of identity, and is subject to the requirements for label statement of optional ingredients, prescribed for whole wheat flour by § 15.080, except that cleaned durum wheat, instead of cleaned wheat other than durum wheat and red durum wheat, is used in its preparation.*

§ 15.110 Crushed wheat, coarse ground wheat—identity. Crushed wheat, coarse ground wheat, is the food prepared by so crushing cleaned wheat other than durum wheat and red durum wheat that, when tested by the method prescribed in § 15.080 (e) (2), 40 percent or more passes through a No. 8 sieve and less than 50 percent passes through a No. 20 sieve. The proportions of the natural constituents of such wheat, other than moisture, remain unaltered. Crushed wheat contains not more than 15 percent of moisture as determined by the method prescribed in "Official and Tentative Methods of Analysis of the Association of Official Agricultural Chemists", [illegible] edition, 1940, page 353, under "Preparation of Sample—Official" and "Moisture I. Drying with Heat—Official."*

§ 15.120 Cracked wheat—identity. Cracked wheat is the food prepared by so cracking or cutting into angular fragments cleaned wheat other than durum wheat and red durum wheat that, when tested by the method prescribed in § 15.080 (c) (2), not less than 90 percent passes through a No. 8 sieve and not more than 20 percent passes through a No. 20 sieve. The proportions of the natural constituents

of such wheat, other than moisture, remain unaltered. Cracked wheat contains not more than 15 percent of moisture as determined by the method prescribed in "Official and Tentative Methods of Analysis of the Association of Official Agricultural Chemists", 5th edition, 1940, page 353, under "Preparation of Sample—Official" and "Moisture I. Drying with Heat—Official."

§ 15.130 Farina—identity. (a) Farina is the food prepared by grinding and bolting cleaned wheat, other than durum wheat and red durum wheat, to such fineness that, when tested by the method prescribed in paragraph (b) (2), it passes through a No. 20 sieve, but not more than 3 percent passes through a No. 100 sieve. It is freed from bran coat, or bran coat and germ, to such extent that the percent of ash therein, calculated to a moisture-free basis, is not more than 0.6 percent. Its moisture content is not more than 15 percent.

(b) For the purposes of this section:

(1) Ash and moisture are determined by the methods therefor referred to in § 15.000 (c).

(2) The method referred to in paragraph (a) is as follows: Use No. 20 and No. 100 sieves, having standard 8-inch full height frames, complying with the specifications for wire cloth and sieve frames in "Standard Specifications for Sieves," published March 1, 1940, in L. C. 584 of the U. S. Department of Commerce, National Bureau of Standards. Fit a No. 20 sieve into a No. 100 sieve. Attach bottom pan to the No. 100 sieve. Pour 100 grams of the sample into the No. 20 sieve. Attach cover and hold the assembly in a slightly inclined position with one hand. Shake the sieves by striking the sides against the other hand with an upward stroke, at the rate of about 150 times per minute. Turn the sieves about one-sixth of a revolution, each time in the same direction, after each 25 strokes. Continue shaking for two minutes. Weigh the material which fails to pass through the No. 20 sieve and the material which passes through the No. 100 sieve.

§ 15.140 Enriched farina—identity; label statement of optional ingredients. (a) Enriched farina conforms to the definition and standard of identity prescribed for farina by § 15.130, except that:

(1) it contains in each pound not less than 1.66 milligrams of vitamin B_1, not less than 1.2 milligrams of riboflavin, not less than 6 milligrams of nicotinic acid or nico-

tinic acid amide, and not less than 6 milligrams of iron (Fe);

(2) vitamin D may be added in such quantity that each pound of the finished enriched farina contains not less than 250 U. S. P. units of the optional ingredient vitamin D;

(3) Calcium may be added in such quantity that each pound of the finished enriched farina contains not less than 500 milligrams of the optional ingredient calcium (Ca);

(4) it may contain not more than 8 percent by weight of the optional ingredient wheat germ or partly defatted wheat germ;

(5) it may contain not less than 0.5 percent and not more than 1 percent by weight of the optional ingredient disodium phosphate; and

(6) In determining whether the ash content complies with the requirements of this regulation allowance is made for ash resulting from any added iron or salts of iron or calcium, or from any added disodium phosphate, or from any added wheat germ or partly defatted wheat germ.

Iron and calcium may be added only in forms which are harmless and assimilable. Dried irradiated yeast may be used as a source of vitamin D. The substances referred to in subparagraphs (1) and (2) may be added in a harmless carrier which does not impair the enriched farina; such carrier is used only in the quantity necessary to effect an intimate and uniform admixture of such substances with the farina.

(b) When the optional ingredient disodium phosphate is used, the label shall bear the statement "Disodium phosphate added for quick cooking." Whenever the name of the food appears on the label so conspicuously as to be easily seen under customary conditions of purchase, such statement shall immediately and conspicuously precede or follow such name, without intervening written, printed, or graphic matter; except that where such name is a part of a trade-mark or brand, other written, printed, or graphic matter, which is also a part of such trade-mark or brand, may so intervene if such statement is in such juxtaposition with such trade-mark or brand as to be conspicuously related to such name.

§ 15.150 Semolina—identity. (a) Semolina is the food prepared by grinding and bolting cleaned durum wheat to such fineness that, when tested by the method prescribed in § 15.130 (b) (2), it passes through a No. 20 sieve, but not more than 3 percent passes through a No. 100 sieve. It is

freed from bran coat, or bran coat and germ, to such extent that the percent of ash therein, calculated to a moisture-free basis, is not more than 0.92 percent. Its moisture content is not more than 15 percent.

(b) For the purpose of this section:

Ash and moisture are determined by the methods therefor referred to in § 15.000 (c).

This order shall become effective on January 1, 1942.

Washington, D. C., May 26, 1941.

W. B. Miller,
Acting Administrator.

(Seal)

[F. R. Doc. 41-3761; Filed, May 26, 1941; 11:57 a. m.]

Endorsed: United States Circuit Court of Appeals. * * (Caption—7765) * * Petition for Review of Order of the Federal Security Administrator. Filed Aug. 22, 1941. Kenneth J. Carrick, Clerk.

UNITED STATES CIRCUIT COURT OF APPEALS.

Filed Oct. 10, 1941.

* * (Caption—7765) * *

PETITIONER'S DESIGNATION OF THE PORTIONS OF THE TRANSCRIPT OF RECORD TO BE CONTAINED IN THE PRINTED RECORD.

The Quaker Oats Company, Petitioner, by George I. Haight, Ward Ross, William D. McKenzie and James Best, its attorneys, hereby designates the following portions of the transcript of record to be contained in the printed record:

1. Petition for Review of Order of the Federal Security Administrator, except Exhibit "A" attached thereto which is covered in Paragraph No. 7 hereof.

2. That part of Government Exhibit 1 which is Notice of Federal Security Agency, Docket FDC-21, of Public Hearings appearing in the Federal Register issue of Saturday, August 3, 1940, at pages 2746 to 2749, including the caption thereof, but excluding Sections 15.000 to 15.070 inclusive, and excluding Section 15.090.

3. That part of Government Exhibit 2 which is Notice of Federal Security Agency, Docket FDC-21, concerning postponement of the opening of public hearings, appearing in the Federal Register issue of Friday, August 9, 1940, at page 2800, including the caption.

4. Notice of Federal Security Agency, Docket FDC-21, of reconvention of hearings appearing in the Federal Register issue of Friday, October 11, 1940, page 4058, including the caption thereof.

5. Proposed Order, Proposed Findings of Fact and Proposed Regulations of the Federal Security Agency, Docket FDC-21, appearing in the Federal Register issue of Tuesday, April 1, 1941, pages 1729 to 1737, including the caption thereof, but excluding Findings of Fact 1 to 32 inclusive, 46 to 73 inclusive, and 87 to 92 inclusive, and excluding Sections 15.000 to 15.120 inclusive, and excluding Section 15.150.

6. Correction by Federal Security Agency, Docket FDC-21, appearing in the Federal Register issue of Tuesday, April 8, 1941, page 1827, including the caption thereof.

7. Final Order, Findings of Fact, and Regulation entered and adopted by Federal Security Agency on May 26, 1941, and appearing in the Federal Register issue of Tuesday, May 27, 1941, pages 2574 to 2582 inclusive, including the caption thereof, but excluding Findings of Fact Nos. 1 to 32 inclusive, 46 to 73 inclusive, and 87 to 92 inclusive, and excluding Sections 15.000 to 15.120 inclusive, and excluding Section 15.150.

8. The following pages of the transcript of the proceedings:

(a) Alanson W. Willcox, Presiding Officer, Tr. p. 9, L. 1 to p. 13, L. 16.

(b) Dr. Henry T. Scott, Tr. p. 398, L. 20 to p. 430, L. 7.

(c) Dr. Frank Gunderson, Tr. p. 430, L. 19 to p. 433, L. 4.

(d) Testimony of Mr. Jos. Calloway, Jr., Dr. Virrell E. Munsey, Dr. Frank Gunderson, Tr. p. 1000, L. 1 to p. 1043, L. 1.

(e) Dr. Frank S. Harris, Tr. p. 1417, L. 6 to p. 1518, L. 8.

(f) Dr. Henry T. Scott, Tr. p. 1702, L. 18 to p. 1726, L. 15.

9. The following Exhibits:

(a) Wisconsin Alumni Research Foundation, Exhibit S.
Wisconsin Alumni Research Foundation, Exhibit T.
Wisconsin Alumni Research Foundation, Exhibit U.
Wisconsin Alumni Research Foundation, Exhibit V.
Wisconsin Alumni Research Foundation, Exhibit W.
Wisconsin Alumni Research Foundation, Exhibit Y.
Wisconsin Alumni Research Foundation, Exhibit AA.
Wisconsin Alumni Research Foundation, Exhibit BB.

(b) The Quaker Oats Company, Exhibit CC.

10. Pertinent Pleadings:

(a) Document entitled "Exceptions of The Quaker Oats Company to the Proposed Order, Proposed Findings of Fact, and Proposed Regulation, as published in the Federal Register for April 1, 1941, at pages 1729 through 1937," dated April 18, 1941.

(b) Exceptions No. 10 to 12 both inclusive, appearing on pages 3 and 4 of the document entitled "Exceptions of the Wisconsin Alumni Research Foundation to the Proposed Order and Memorandum Brief in Support Thereof," dated April 18, 1941.

(c) Exception 2 under heading "Section 15.140, Enriched Farina-Identity," appearing on pages 10 to 11 of the document entitled "Exceptions of the Millers' National Federation to the Proposed Order, Proposed Findings of Fact, and Proposed Regulation and Brief in Support Thereof," dated April 19, 1941, and Exception 2 appearing in said document under the heading "In General" on pages 12 to 13 thereof.

(d) Exception 2 under the heading "General Exceptions" appearing on page 15 of the document entitled "Exception of Pillsbury Flour Mills Company to the Proposed Order, Proposed Findings of Fact, and Proposed Regulation, and Brief in Support Thereof," dated April 19, 1941, and Exception 2 on page 23 thereof.

11. Certification of the Record.

The Quaker Oats Company,
Petitioner,

By George I. Haight,
Ward Ross,
William D. McKenzie,
James Best,
Attorneys for Petitioner,
209 South La Salle Street,
Chicago, Illinois.

Dated: Chicago, Illinois, October 9, 1941.

Endorsed: U. S. Circuit Court of Appeals. * * Caption—7765) * * Petitioner's Designation of the Portions of the Transcript of Record to Be Contained in the Printed Record. Filed Oct. 10, 1941. Kenneth J. Carrick, Clerk.

Filed Nov. 3, 1941.

UNITED STATES CIRCUIT COURT OF APPEALS.

• • (Caption—7765) • •

RESPONDENTS DESIGNATION OF ADDITIONAL PORTIONS OF THE TRANSCRIPT TO BE ADDED TO THE PRINTED RECORD.

The respondent, Federal Security Administrator, by his attorneys, Wendell Berge, William W. Barron, and Louis B. Schwartz, hereby designates the following portions of the transcript to be added to the designations heretofore filed by petitioner for the printed record.

1. Caption and complete text of the notice of public hearings in F.D.C.-21 set forth at pp. 2746-2749 of Gov. Ex. 1. (This embraces petitioner's designation 2.)

2. Caption and complete text of Proposed Order, Proposed Findings of Fact, and Proposed Regulations, in F.D.C.-21 set forth in the Federal Register of Tuesday, April 1, 1941, pp. 1729-1737. (This embraces petitioner's designation 5.)

(3. Caption and complete text of Final Order, Findings of Fact and Regulation in F.D.C.-21 set forth in the Federal Register for May 27, 1941, at pp. 2574-2582. (This embraces petitioner's designation 7.)

4. The following pages of the transcript of the proceedings: Figures in parentheses refer to the beginning and ending lines on the respective pages. Where the figure in parentheses is negative, count up from bottom of page.

14(10)-16(12); 17(7)-38(13); 40(14)-44(11);
'86(15)-95(12); 97(14)-103(18); 155 (entire); 325(1)-375(12);
382(12)-439(9) (includes petitioner's designations 8(b) and (c));
442(5)-465(-2); 467(3)-477(13); 479(2)-518(2); 522 (entire);
523(18)-526(2); 529(4)-529(24); 547(14)-551 (end); 556(-2)-569(3); 570(16)-572(17); 587(11)-606(6); 630(1)-633(-5);
668(6)-681(7); 687(-1) (beg. "We realize • • •")-688(13);
689(1)-691 (end); 692(10)-694(6); 700(14)-704 (end);
705(17)-(end); 707(9)-715(-5); 750(6)-778(9); 779(5)-782(-2);

839(9)-852(1); 889 (entire); 1194 (entire); 1272(4)-1275 end);
1296(1)-1298(1); 1311(6)-1311(14); 1313(1)-1325(4);
1333(9)-1336(22); 1367(1)-1368(10); 1374(17)-1818(19) (includes petitioner's designation 8(e) and (f)); 1820(20)-1827(17); 1927(1)-1962(17).

5. Table XVII (Farina) in Gov. Ex. 3.
6. General Mills' Ex. E.
7. Other Parties' Exhibits 0(1), P, Q, R, EE.
8. Report of presiding officer in F.D.C. 21, pp. 1(1)-2(2); 8(5)-end of page; and 12(17)-20(-7).
9. Folio paging so far as practicable.

Wendell Berge,
Wendell Berge,
William W. Barron,
William W. Barron,
Louis B. Schwartz,
Louis B. Schwartz,
Counsel for Respondent.

Service acknowledged ..... 19 .....

Counsel for Petitioner.

Filed Nov. 7, 1941.

UNITED STATES CIRCUIT COURT OF APPEALS.

• • (Caption—7765) • •

PETITIONER'S DESIGNATION OF ADDITIONAL PORTIONS OF THE TRANSCRIPT OF RECORD TO BE CONTAINED IN THE PRINTED RECORD.

The Quaker Oats Company, Petitioner, by George I. Haight, William D. McKenzie, James M. Best and Ward Ross, its attorneys, hereby designates the following portion of the transcript of record to be added to the designations heretofore filed by petitioner and by respondent in the printed record:

Transcript page 1743, lines 12 to 18.

The Quaker Oats Company,
Petitioner,

By George I. Haight,
Ward Ross,
William D. McKenzie,
James W. Best,
Attorneys for Petitioner.

Dated, Chicago, Illinois, November 6th, 1941.

Endorsed: U. S. Circuit Court of Appeals. • • Caption—7765) • • Petitioner's Designation of Additional Portions of the Transcript of Record to Be Contained in the Printed Record. Filed Nov. 7, 1941. Kenneth J. Carrick, Clerk.

At a regular term of the United States Circuit Court of Appeals for the Seventh Circuit, held in the City of Chicago and begun on the first day of October, in the year of our Lord one thousand nine hundred and forty, and of our Independence the one hundred and sixty-fifth.

7765

THE QUAKER OATS COMPANY, PETITIONER

vs.

FEDERAL SECURITY ADMINISTRATOR, RESPONDENT

Petition for Review of Order of the Federal Security Administrator

And, to wit: On the twenty-sixth day of June 1942 there was filed in the office of the Clerk of this Court, the opinion of the Court, which said opinion is in the words and figures following, to wit:

In the United States Circuit Court of Appeals for the Seventh Circuit

No. 7765. October Term, 1941, April Session, 1942.

THE QUAKER OATS COMPANY, PETITIONER

vs.

FEDERAL SECURITY ADMINISTRATOR, RESPONDENT

Petition for Review of Order of the Federal Security Administrator

June 26, 1942

Before SPARKS, MAJOR, and MINTON, Circuit Judges.

MAJOR, Circuit Judge: This is a petition for review of respondent's order, entered May 26, 1941, promulgating regulations fixing and establishing definitions and standards of identity for "farina" and "enriched farina" and numerous related flour mill products.

The authority relied upon by respondent is contained in Section 341, Title 21, U. S. C. A. Supp., entitled "Definitions and Standards for Food." (Section numbers used in this opinion refer to U. S. C. A.) The section, so far as here material, provides:

"Whenever in the judgment of the Administrator such Action will promote honesty and fair dealing in the interest of consumers, he shall promulgate regulations fixing and establishing for any food, under its common or usual name so far as practicable, a reasonable definition and standard of identity, a reasonable standard of quality, and/or reasonable standards of fill of container: * * *"

The Administrator, after notice and hearings participated in by members representing the pertinent industry, as well as consumer representatives, adopted findings of fact and concluded on the basis thereof that the regulations included in his order would promote honesty and fair dealing in the interest of consumers. Then follows the regulations fixing standards for a large number of flour products, as well as those involved in this proceeding, namely "farina" and "enriched farina." The former, designated as Reg. 15.130, defines farina as the food prepared by grinding and bolting clean wheat, other than durum wheat and red durum wheat, to a prescribed fineness, with bran coat and germ removed to the extent that the percentage of ash in the final product, calculated to a moisture free basis, does not exceed .6 percent. The latter, designated as Reg. 15.140, defines enriched farina as conforming to the standard fixed for farina, except that it contains prescribed minimum quantities of vitamin B_1, riboflavin, nicotinic acid, and iron. Enriched farina, under the Administrator's standard, may contain as optional additional ingredients vitamin D, calcium, wheat germ, and disodium phosphate.

While there is some disagreement as to the contested issues involved, we think they may be fairly summarized by petitioner's contention, disputed by respondent, that each of the regulations is unreasonable, that they do not promote honesty and fair dealing in the interest of consumers, and are not supported by substantial evidence. Furthermore, it is contended by petitioner that respondent was without authority to promulgate a regulation concerning enriched farina which had not been marketed theretofore, that the notice of the hearing did not purport to authorize the reception of evidence concerning such standard and that, as a matter of fact, evidence was not received pertinent thereto. It is also contended with respect to both standards that respondent, in administering the Act, has reached an unconstitutional result.

The basis upon which we think this case must be decided makes it unnecessary to enter into a discussion as to the character of notice given by respondent. It is sufficient to state that while petitioner's contention is not without merit, yet we are of the view that its participation in the hearings, both the original and the adjourned, were such as to preclude it from successfully invoking such issue. Likewise, we think it is unnecessary to enter into a

discussion of petitioner's contention that the findings are without substantial support. For the purpose of this opinion (with certain exceptions noted hereinafter) we accept them.

It is, therefore, sufficient to summarize the findings as made by respondent. A major portion of the hearings was devoted to the numerous grades of flour and only a minor portion to farina. As a consequence, most of the findings, strictly speaking, pertain to flour, which petitioner contends have no relevancy to farina and were, therefore, improperly included in the record. It must be conceded, we think, that there is such a close relationship between flour or, at any rate, some of the grades thereof, and farina, that it would be impractical, if not impossible, to consider the evidence and findings concerning the latter without giving consideration to the former.

Farina is a product obtained by grinding wheat and separating the bran coat and germ of the grain from the endosperm. It consists essentially of endosperm in particles larger than permissible in flour, the size of the particles being the principal characteristic distinguishing the product from flour. In fact, it corresponds substantially to a fine grade of white flour known as "Patent Flour." It is used as a breakfast food, as an ingredient of macaroni products and extensively as a cereal food for children.

It was found that the removal of the bran coat and germ in the manufacture of flour and farina eliminates those parts of the wheat which are richest in vitamins and minerals. It was also found there exists a serious and widespread nutritional deficiency in children, as well as in adults, of vitamin B_1, riboflavin, nicotinic acid, iron, calcium, and vitamin D. These elements are available as synthetic compounds and are suitable for the enrichment of flour and farina. It was further found that vitamin D and calcium are used singly as enrichments of flour and farina, but consumer education has generally recommended dairy products as the most desirable source of the calcium and milk as the product most suitable for enrichment with vitamin D. It was found, however, that the addition of D and calcium as optional ingredients in enriched flour and enriched farina would be useful for those who consume insufficient dairy products.

It was found that manufacturers have recently placed on the market flours and farinas enriched with one or more of these nutritional elements.[1] The composition of these enriched products varies widely, as it is found, and unless a standard limiting the kinds and amounts of enrichment is adopted, the manufacturers' selection of nutritional elements is likely to lead to a great diversity

[1] The ruling must refer largely to flours, as the record discloses only two farinas to which vitamins have been added.

of enrichments, both quantitative and qualitative. Such diversity would tend to confuse and mislead consumers as to the relative value and need of the several nutritional elements, and would impede rather than promote honesty and fair dealing in the interest of consumers. Indiscriminate enrichment with vitamins and minerals would tend to confuse and mislead consumers by giving rise to conflicting claims regarding the beneficial effects of various vitamins and minerals; and would be likely to lead to the impression on the part of consumers that a single article of food, so enriched, would meet all nutritional needs.

It was also found that, pending experience with the use of enriched flour and enriched farina, consumer education and understanding would be facilitated by restriction of enrichment with respect to the ingredients and, as to farina, the minimum amounts of such ingredients. The findings further recite that flour and farina enriched with vitamins and minerals have not acquired common or usual names, but that such products may be accurately designated as "enriched flour" and "enriched farina."

Upon the basis of such findings, respondent concluded that it would "promote honesty and fair dealing in the interest of consumers" to adopt the standards of identity for farina and enriched farina embodied in the regulations in controversy. The record discloses certain other evidence not specifically covered by the findings, but not inconsistent therewith, to which we briefly refer.

Petitioner has, since April 1932, sold its product, labeled on the front panel of the package, "Quaker Farina Wheat Cereal, enriched with vitamin D," or "Quaker Farina enriched by the Sunshine Vitamin." On the back panel of the package is the following description:

> "contains 400 U. S. P. units of Vitamin D per ounce, supplied by approximately the addition of 1/4th of 1 per cent irradiated dry yeast."

During such period it has sold millions of packages annually and its product is of national reputation.

Vitamin D functions in regulating the metabolism of calcium and phosphorus in the body and is, therefore, concerned with the proper formation of bones and teeth. It is recognized as especially beneficial in the infant and growing child as a preventative and therapy of rickets and the building of strong bones and teeth. It is also an essential vitamin for adults. There is medical testimony to the effect that of all known vitamins, it is the one most deficient in normal diet and should, therefore, be supplied in foods which are consumed regularly by the great mass of population, particularly those in the low income groups. While the Administrator found that milk was the most appropriate

carrier for vitamin D, it is not disputed but that farina is also a proper carrier. Vitamin D in nature is found almost exclusively in sunshine and certain fish livers which are unavailable to humans in the normal diet. Therefore, as we understand, this vitamin is deficient in ordinary food products, except when artificially supplied.

Thus, we have a situation where farina, with the addition of vitamin D, as manufactured and marketed by petitioner, is admittedly a wholesome and healthful product (it is admitted in respondent's brief that vitamin D is a beneficial substance), and that it has been sold to millions of consumers, without deception, fraud, or misrepresentation of any kind or character. As already pointed out, the regulations in question permit the manufacture and sale of plain farina and enriched farina. The regulation as to the former, in effect, prohibits petitioner from the sale of farina to which vitamin D has been added, as has long been its practice. The regulation as to the latter permits the use of vitamin D as an optional ingredient in connection with other vitamins, the use of which is mandatory.

Respondent criticizes, without merit we think, petitioner's treatment of the standards as separate and distinct. It is said they must be considered together, or, at any rate, with reference to each other. Such consideration, however, as we view the matter, furnishes little, if any, assistance to respondent's cause.

This brings us to what we regard as the heart of the controversy, embracing the issue as to respondent's authority to promulgate the regulations in dispute. Closely allied therewith is the question as to the reasonableness of the regulations, even if found to be within the authority conferred by the Act.

We assume there could be no dissent from the proposition that an administrative agency has only such authority in the administration of a Congressional enactment as is expressly conferred, or as may be reasonably implied. Prior to discussing the matter of respondent's authority, we again refer briefly to the findings of fact by which we are bound, if supported by substantial evidence. Sec. 371 (f) (3). As already noted, we accept the findings with certain exceptions, one of which may, or may not, be a finding, viz, that the regulations in suit will promote honesty and fair dealing in the interest of consumers. We assume from respondent's argument that this is regarded as a finding of fact, notwithstanding its being labeled as a conclusion and predicated upon the facts as found. Other than this labeled conclusion, the only reference in 92 findings to honesty and fair dealing is found in connection with the discussion as to the diversity of products of various manufacturers which, it is found, would "tend to confuse and mislead consumers * * * and would im-

pede rather than promote honesty and fair dealing in the interest of consumers." The conclusion that the regulations will promote honesty and fair dealing comes closer, in our judgment, to being one of law than of fact. If so, we are not bound to accept it. On the other hand, if it be considered as a finding of fact, we are of the view that it is without substantial support.

All of the findings, labeled as such, as well as respondent's argument before this court, are bottomed upon the premise that the standards in controversy are authorized because they are in the interest of the consumer. As stated in his brief:

"The real issue, of course, is whether the requirements of the regulation are reasonably related to the promotion of consumers' interests. * * *"

A study of the record leaves no room for doubt but that the hearing revolved largely around consumer interest as it related to health. In referring to the ingredients of enriched farina, it is stated in respondent's brief: "They are essential to the health and well being of our nation." In support of the regulations it is also suggested that they will prevent confusion among consumers as to their nutritional needs. In this regard, respondent states:

"* * * Indiscriminate enrichment with vitamins and minerals would tend to confuse and mislead consumers by giving rise to conflicting claims regarding the beneficial effects of various vitamins and minerals and would be likely to lead to the impression on the part of consumers that a single article of food so enriched would meet all nutritional needs. * * *"

It is still further suggested that the regulations will promote consumer understanding of the relative value of enriched and natural foods.

As is shown by the statutory provision quoted heretofore, the Administrator is authorized to promulgate regulations fixing standards whenever, in his judgment, "such action will promote honesty and fair dealing in the interest of consumers." Thus, his action in the interest of consumers is expressly limited to the promotion of honesty and fair dealing in their behalf.

That the promotion of honesty and fair dealing was intended by Congress to mean something other than the promotion of the consumers' health is plainly ascertainable from a study of the Act. Likewise, it is clear that action was not authorized merely to avoid confusion on the part of consumers, nor to educate the public as to dietary requirements. If Congress had so intended, it would, no doubt, have employed the appropriate language. While there may be some relevancy between the promotion of health and that of honesty and fair dealing, they certainly are

not synonymous terms. Injury to health does not necessarily follow from dishonesty and unfair dealing in food products, and neither does health improvement necessarily follow from honesty and fair dealing.

That Congress used the words "honesty and fair dealing" in their ordinary sense, we think there is little room to doubt. The general rule that legislative words must be so construed, is strengthened, so we think, by a reading of the Act which became a law June 25, 1938, entitled "Federal Food, Drug and Cosmetic Act." It is divided into seven subchapters, including subchapter 4 relating to food, the one now under consideration. Under this subchapter, Section 341 defines the Administrator's authority for the fixing of standards. In addition to the language quoted heretofore from this section, it contains a clause, as follows:

"* * * In prescribing a definition and standard of identity for any food or class of food in which optional ingredients are permitted, the Administrator shall, for the purpose of promoting honesty and fair dealing in the interest of consumers, designate the optional ingredients which shall be named on the label. * * *"

In other words, telling the consumer the truth as to optional ingredients is declared to be in the promotion of honesty and fair dealing. The lawmakers evidently did not contemplate the dietary requirements of consumers, the likelihood of confusion relative thereto, or their need for education as constituting a basis for the promotion of honesty and fair dealing.

Section 342 is entitled "Adulterated Food" and describes the conditions under which a food shall be deemed to be adulterated. It contains such designations as poisonous or deleterious to health, filthy, putrid, decomposed, substitution, and concealment. Section 343 is entitled "Misbranded Food" and Paragraphs (a) to (k), inclusive, describe such foods. Terms are employed such as false or misleading label, offering for sale under another name, imitation of another food, misleading container, and artificial flavoring. Paragraph (g) describes as misbranded a food represented as one for which a standard has been prescribed unless (1) it conforms to such definition and standard, and (2) its label bears the name specified in the standard and, insofar as required by the regulation, the name of any optional ingredients. It will thus be observed that the truth as to a food for which a standard has been fixed permits it to escape the indictment of being misbranded.

If defendant's contention be accepted that he has the authority to fix a standard as to the ingredients of a food which is truthfully labeled, then it would seem to follow that the statute indicts as misbranded that which, as a matter of fact, is correctly branded. This is the tortious result achieved by attempting to promote a

dietary standard rather than honesty and fair dealing, as the Statute requires. The result is all the more obnoxious in the instant situation where, as already pointed out, the consumer is adequately and truthfully informed as to petitioner's product which, in addition, is in no way deleterious to the health of the consumer.

Our discussion, designed to show that a standard food, although in the interest of the consumer, does not meet the test of honesty and fair dealing, is further strengthened by a study of subchapter V relating to drugs. As noted, this is a part of the same Act and enacted at the same time. While we make no attempt to construe this sub-chapter, a study of it readily discloses that the intention was to prohibit the sale of drugs under false, misleading, and deceptive labels. In other words, it was sought to protect the consumer by requiring that he be truthfully informed as to the contents of the drug offered for sale. Illustrative is Section 352 (d) which removes habit-forming drugs from the misbranded class where the label correctly bears the name and quantity of the ingredient, with the warning that it may be habit-forming. It seems unreasonable to think that Congress intended to apply the odious term "misbranded" to a food product correctly labeled and admittedly wholesome and beneficial, and permit drugs to escape such designation by the means of a truthful and honest label.

The findings and argument predicated upon the possibilities for confusion of consumers, in optional partial enrichment, carry little, if any, weight. There was no evidence in support of such possibilities and they are entirely speculative and conjectural. As was said in Federal Trade Commission v. Raladam Company, 283 U. S. 643, 653:

"* * * All this was left without proof and remains, at best, a matter of conjecture. Something more substantial than that is required as a basis for the exercise of the authority of the Commission."

Looking at the realities of the situation, it is difficult to perceive how consumers' confusion, resulting from the truth as to the ingredients of a product, could support an action to promote honesty and fair dealing.

Furthermore, we should think that a product manufactured in accordance with the regulations in suit would tend to increase rather than retard confusion. This is especially true as to enriched farina. No such product has been sold heretofore under that designation. The manufacturer will be required only to label it "enriched farina" unless the option to add vitamin D is exercised, in which case such addition must be stated. How the ordinary consumer will be informed so as to avoid confusion

as to what is meant by enriched farina, its contents, or the benefits to be expected from its use, is a mystery which we are not able to fathom. How the contention that confusion is likely to result from a product, such as petitioner's, which truthfully informs the consumer as to what he is buying, can be reconciled with the contention that a product sold as enriched farina, without any further description, will lessen or avoid confusion, is beyond our comprehension.

Another unreasonable and, we think, arbitrary result of these regulations is that petitioner is precluded from adding vitamin D to its product, as it has done for many years and, at the same time, permitted to add vitamin D as an optional ingredient in enriched farina. We say it is unreasonable for the reason that no claim is made of any relationship or coaction between vitamin D and the other ingredients required in enriched farina. As a result, the consumer who is deficient in vitamin D only, as is often the case, must buy a product containing vitamins and ingredients which he does not need, or does not want, in order to obtain the benefit of vitamin D. Another unreasonable result, so we think, is that by the exclusion of vitamin D from petitioner's product, many people will be deprived of this admittedly essential vitamin. This result is none the less real by reason of the suggestion that milk is the most appropriate carrier of vitamin D, and that the majority of consumers (infants and children) who use petitioner's product are also large consumers of milk. There might be merit to this suggestion but for the fact that vitamin D is not a substantial ingredient of milk or any other natural food product in ordinary use. Thus, in order to obtain this essential vitamin in milk, it must be added thereto. Looking at the realities of the situation, we think this would mean that very few of the so-called low income group would receive sufficient vitamin D. Too many of them, no doubt, are without the necessary amount of milk, much less milk to which this vitamin has been added. So, as a final result, the regulations are responsible for a situation whereby a consumer is precluded from obtaining vitamin D alone in connection with farina; he may get it in connection with enriched farina at the option of the manufacturer, or he may get it with his milk, provided he possesses the foresight to see that it is added thereto.

Respondent relies strongly upon United States v. Carolene Products Co., 304 U. S. 144, wherein the court sustained the validity of an act which prohibited the shipment in interstate commerce of skimmed milk compounded with any fat or oil other than milk fat, so as to resemble milk or cream. We think this case furnishes respondent's position little, if any, support. The

court, in commenting upon the Congressional hearings, on page 149, said:

"* * * Both committees concluded, as the statute itself declares, that the use of filled milk as a substitute for pure milk is generally injurious to health and facilitates fraud on the public." *

and again, on page 151, it stated:

"Here the prohibition of the statute is inoperative unless the product is 'in imitation or semblance of milk, cream, or skimmed milk, whether or not condensed.' * * *"

As these quotations indicate, the court was considering legislation concerning a product which Congress concluded was injurious to health and a fraud upon the public. It was pointed out that the inferior product was indistinguishable from pure milk "thus making fraudulent distribution easy and protection of the consumer difficult." In the instant situation, however, there is nothing about the appearance of the product facilitating fraud upon the consumer. True, as the record discloses, plain farina, petitioner's farina, and enriched farina are indistinguishable in appearance and taste. Petitioner's product, however, is in no sense a substitution, an imitation, or injurious to health. Therefore, if the condemning language of the Carolene case is applicable to petitioner's product, which we think it is not, it is also applicable to plain farina and enriched farina. So far as appearance and taste are concerned, there is no more likelihood of the consumer being deceived or confused as to petitioner's product than as to either of the others. Furthermore, the court in the Carolene case was dealing with the power of Congress, while here we are considering the authority which Congress has conferred upon the Administrator, and the reasonableness of his action.

Hebe Company v. Shaw, 248 U. S. 297, is also relied upon by respondent. This case was cited and relied upon in the Carolene case (p. 148), and, we think, is likewise distinguishable. The element of fraudulent substitution was present in both cases.

We have not overlooked respondent's argument that courts will not substitute their judgment for that of an Administrative Agency on the wisdom or expediency of a determination within its jurisdiction. There is no occasion to cite or comment upon cases cited in support of this argument. We do not take issue—in fact, we agree. The rule, however, is of no benefit to respondent in the instant situation because, as we have endeavored to show the regulations, while purporting to be in the interest of consumers, do not promote honesty and fair dealing in their behalf. On this statutory requirement, essential to respondent's authority

to act, the record is wholly deficient. In view of this situation, the action of respondent, in promulgating the regulations in controversy, was beyond his statutory authority. Such being the case, they must be set aside. It is so ordered.

A true Copy:
Teste:

Clerk of the United States Circuit Court of Appeals for the Seventh Circuit.

And on the same day, to wit: On the twenty-sixth day of June 1942 the following further proceedings were had and entered of record, to wit:

Friday, June 26, 1942

Court met pursuant to adjournment.

Before: Hon. WILLIAM M. SPARKS, Circuit Judge; Hon. J. EARL MAJOR, Circuit Judge; Hon. SHERMAN MINTON, Circuit Judge.

7765

THE QUAKER OATS COMPANY, PETITIONER

vs.

FEDERAL SECURITY ADMINISTRATOR, RESPONDENT

Petition for Review of Order of the Federal Security Administrator

This cause came on to be heard on the transcript of the record from the Federal Security Agency, and was argued by counsel.

On consideration whereof, it is ordered and adjudged by this Court that the order of the Federal Security Administrator entered on May 26, 1941, be, and the same is hereby, set aside.

United States Circuit Court of Appeals For the Seventh Circuit

I, Kenneth J. Carrick, Clerk of the United States Circuit Court of Appeals for the Seventh Circuit, do hereby certify that the foregoing typewritten and printed pages contain a true copy of the opinion filed June 26, 1942, and the judgment entered thereon June 26, 1942, in the following entitled cause: Cause No. 7765—The Quaker Oats Company, petitioner, vs. Federal Security Administrator, respondent—as the same remains upon the

files and records of the United States Circuit Court of Appeals for the Seventh Circuit.

In testimony whereof I hereunto subscribe my name and affix the seal of said United States Circuit Court of Appeals for the Seventh Circuit, at the City of Chicago, this fourteenth day of September A. D. 1942.

[SEAL] KENNETH J. CARRICK,
Clerk of the United States Circuit Court of Appeals for the Seventh Circuit.

U. S. GOVERNMENT PRINTING OFFICE 1942

Supreme Court of the United States

No. 424, October Term, 1942

Order allowing certiorari .

Filed November 9, 1942

The petition herein for a writ of certiorari to the United States Circuit Court of Appeals for the Seventh Circuit is granted.

And it is further ordered that the duly certified copy of the transcript of the proceedings below which accompanied the petition shall be treated as though filed in response to such writ.

U. S. GOVERNMENT PRINTING OFFICE: 1943

FILE COPY

SEP 26 1942
CHARLES ELMORE CROPLEY
CLERK

No. 424

In the Supreme Court of the United States

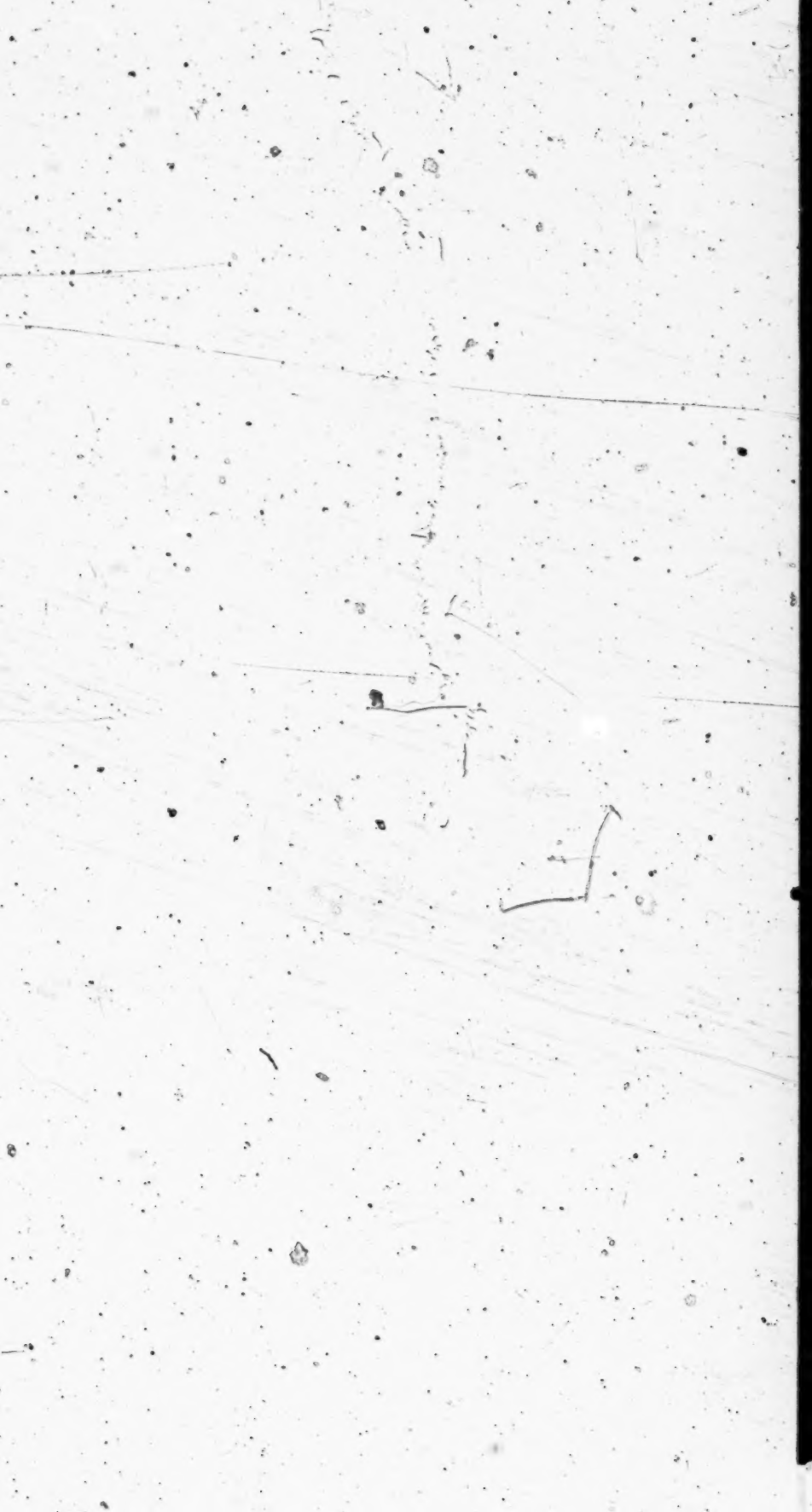
OCTOBER TERM, 1942

FEDERAL SECURITY ADMINISTRATOR, PETITIONER

v.

THE QUAKER OATS COMPANY

PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES CIRCUIT COURT OF APPEALS FOR THE SEVENTH CIRCUIT



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In the Supreme Court of the United States

OCTOBER TERM, 1942

No. ——

FEDERAL SECURITY ADMINISTRATOR, PETITIONER

v.

THE QUAKER OATS COMPANY

PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES CIRCUIT COURT OF APPEALS FOR THE SEVENTH CIRCUIT

The Solicitor General, on behalf of the Federal Security Administrator, prays that a writ of certiorari issue to review the judgment of the United States Circuit Court of Appeals for the Seventh Circuit, entered June 26, 1942, setting aside regulations issued by the Federal Security Administrator under the Federal Food, Drug, and Cosmetic Act of 1938.

OPINION BELOW

The opinion of the Circuit Court of Appeals (R. 679–689) is reported in 129 F. (2d) 76. Regulations 15.130 and 15.140 of the Federal Security Administrator are set forth at R. 637–638.

JURISDICTION

The judgment of the Circuit Court of Appeals was entered on June 26, 1942 (R. 689). The jurisdiction of this Court is invoked under Section 240 (a) of the Judicial Code, as amended by the Act of February 13, 1925, and Section 701 (f) (4) of the Federal Food, Drug, and Cosmetic Act of June 25, 1938, 52 Stat. 1046, 1055.

QUESTIONS PRESENTED

The ultimate question presented is whether regulations 15.130 and 15.140 of the Federal Security Administrator, excluding vitamin D from the definition and standard of identity for "farina" and permitting it only in "enriched farina" in which vitamin B_1, nicotinic acid and iron are required, are reasonable. This question depends in turn principally upon the subsidiary questions:

(a) whether there is substantial evidence in support of the Federal Security Administrator's finding that indiscriminate enrichment of farina with vitamin and mineral supplements would tend to confuse and mislead consumers; and

(b) whether, if so, the Administrator is entitled to consider such tendency to confuse and mislead consumers in reaching the conclusion that it would promote honesty and fair dealing in the interest of consumers to promulgate the standards of identity for farina and enriched farina.

STATUTE INVOLVED

The Federal Food, Drug, and Cosmetic Act of 1938, 52 Stat. 1046, 1055 (21 U. S. C. Sections 341 and 371), in pertinent part, provides as follows:

> SEC. 401. Whenever in the judgment of the Administrator [1] such action will promote honesty and fair dealing in the interest of consumers, he shall promulgate regulations fixing and establishing for any food, under its common or usual name so far as practicable, a reasonable definition and standard of identity, a reasonable standard of quality, and/or reasonable standards of fill of container * * *. In prescribing a definition and standard of identity for any food or class of food in which optional ingredients are permitted, the Administrator shall, for the purpose of promoting honesty and fair dealing in the interest of consumers, designate the optional ingredients which shall be named on the label. * * *
>
> * * * * * *
>
> SEC. 701 (e). The Administrator, on his own initiative or upon an application of any interested industry or substantial portion

[1] The terms "Federal Security Administrator" and "Administrator" have been substituted for the terms "Secretary of Agriculture" and "Secretary" because by Reorganization Plan No. IV, 54 Stat. 1234, the Federal Food and Drug Administration and its functions were transferred to the Federal Security Agency and the functions of the Secretary of Agriculture relating to the administration of the Act were transferred so as to be exercised by the Federal Security Administrator.

thereof stating reasonable grounds therefor, shall hold a public hearing upon a proposal to issue, amend, or repeal any regulation contemplated by any of the following sections of the Act: 401 * * *. The Administrator shall give appropriate notice of the hearing, and the notice shall set forth the proposal in general terms and specify the time and place for a public hearing to be held thereon * * *. At the hearing any interested person may be heard in person or by his representative. As soon as practicable after completion of the hearing, the Administrator shall by order make public his action in issuing, amending, or repealing the regulation or determining not to take such action. The Administrator shall base his order only on substantial evidence of record at the hearing and shall set forth as part of the order detailed findings of fact on which the order is based.

SEC. 701 (f) (1). In a case of actual controversy as to the validity of any order under subsection (e), any person who will be adversely affected by such order if placed in effect may * * * file a petition with the Circuit Court of Appeals of the United States for the circuit wherein such person resides or has his principal place of business, for a judicial review of such order * * *.

* * * * * *

SEC. 701 (f) (3). The court shall have jurisdiction to affirm the order, or to set it aside in whole or in part, temporarily or permanently * * *. The findings of the

Administrator as to the facts, if supported by substantial evidence, shall be conclusive.

STATEMENT

On May 26, 1941, after notice and hearing as prescribed by Sec. 701 (e) of the Act, the Acting Federal Security Administrator promulgated regulations fixing and establishing definitions and standards of identity for "farina" and "enriched farina," and a number of related flour mill products (R. 628–639). Regulation 15.130 defines farina as the food prepared by grinding and bolting cleaned wheat other than durum wheat and red durum wheat to a prescribed fineness, with bran coat and germ removed to the extent that the percentage of ash in the final product, calculated to a moisture free basis, does not exceed .6 percent (R. 637).[2] Enriched farina under Regulation 15.140 is defined as farina conforming to Section 15.130 except that it must contain prescribed minimum quantities of vitamin B_1, riboflavin,[3] nicotinic acid and iron. The regulation also provides that enriched farina may contain as optional ingredients vitamin D, calcium, wheat germ and disodium phosphate (R. 637–639).

[2] The ash content is a measure of the degree of separation and removal of bran coat and germ from the endosperm of the wheat grain. See findings 6–11, 77 (R. 611–612, 625).

[3] Owing largely to the effects of war priorities and lend-lease requirements the effective date of the riboflavin provision has been postponed until April 20, 1943 (7 Fed. Reg., p. 3055, April 25, 1942).

The Quaker Oats Company manufactures a product consisting of plain farina plus vitamin D, which it markets as "Quaker Farina Wheat Cereal Enriched with Vitamin D" or "Quaker Farina Enriched by the Sunshine Vitamin" (R. 640). The Quaker Oats Company filed a petition for judicial review in the court below (R. 640-644) alleging that the effect of the standards for farina and enriched farina is to require it either to cease adding vitamin D and marketing its product as enriched, or to include in any farina which "purports to be or is represented as" enriched farina the prescribed minimum quantities of vitamin B_1, nicotinic acid and iron, in addition to the vitamin D which it now uses.[4] The petition further alleged that the regulations were invalid upon the grounds, *inter alia*, that they were unreasonable, not based upon substantial evidence, and beyond the statutory authority conferred upon the Administrator.

The Administrator's findings of fact relating to farina and the subject of vitamin and mineral enrichment (R. 617-619, 624-627) may be summarized as follows:

Manufacturers have recently placed on the market flours and farinas enriched with one or more vitamins and minerals (R. 617-618, 626). However, the composition of these enriched products varies widely and unless a standard which limits

[4] This allegation was not denied and was conceded by the Administrator in the court below.

the kinds and amounts of enrichment is adopted "the manufacturers' selection of the various nutritive elements and combinations of elements on the basis of economic and merchandising considerations is likely to lead to a great increase in the diversity, both qualitative and quantitative, in enriched flours. • • • Such diversity would tend to confuse and mislead consumers as to the relative value of and need for the several nutritional elements, and would impede rather than promote honesty and fair dealing in the interest of consumers" (R. 618). Indiscriminate enrichment with vitamins and minerals "would tend to confuse and mislead consumers by giving rise to conflicting claims regarding the beneficial effects" of various vitamins and minerals "and would be likely to lead to the impression on the part of consumers that a single article of food so enriched would meet all nutritional needs." On the other hand, "limited enrichment of selected staple foods • • • is readily adapted to the promotion of consumer understanding of the relative value of enriched and natural foods" (R. 618, 636).

The Administrator also found that pending experience with the use of enriched flour and enriched farina, consumer education and understanding would be facilitated by restricting enrichment, not only with respect to the ingredients to be contained

therein, but also by the fixing of minimum and, in the case of flour, maximum amounts of such ingredients (R. 619, 626).

Farina is manufactured by grinding wheat and separating the bran coat and germ of the grain from the endosperm. The finished product consists essentially of endosperm in particles larger than permissible in flour, the size of the particles being the principal characteristic distinguishing the product from flour. Consumers generally expect farina to be almost entirely free from bran coat and germ, and in this respect farina corresponds substantially to a fine grade of white flour known as "patent flour" (R. 624–625). Farina is used as a breakfast food and as an ingredient of macaroni products. It is also extensively used as a cereal food for children and in many cases is the only cereal food used during a period of their growth (R. 626).

The Administrator found that "the removal of bran coat and germ from endosperm in the manufacture of farina removes those parts of the wheat which are richest in vitamins and minerals" (R. 626). Recent investigations of the diets of persons in various sections and in various income groups have shown that in many cases the food consumed does not furnish sufficient amounts of these substances to maintain health. "Among the most serious and widespread deficiencies, in children as

well as adults, are those of vitamin B_1, riboflavin, nicotinic acid, and iron. Deficiencies of these vitamins tend to occur in the same individuals." There is also a deficiency of calcium in certain groups of the population and of vitamin D in large numbers of infants and children. Deficiencies are more prevalent in the cases of persons with low incomes (R. 617).

The Administrator also found that wheat contains a number of essential food elements which are deficient in many diets, including vitamin B_1, riboflavin, nicotinic acid, and iron. These are available as synthetic compounds and are suitable for the enrichment of flour and farina. To a limited extent vitamin D and calcium are also used as enrichments of flour and farina, but consumer education has generally recommended dairy products as the most desirable source of calcium and milk as the product most suitable for enrichment with vitamin D. It was found, however, that the addition of D and calcium as optional ingredients in enriched flour and enriched farina would be useful for those who consume insufficient dairy products (R. 618–619).

The findings further recite that farina enriched with vitamins and minerals has not acquired a common or usual name but that "an accurate designation for the product is 'enriched farina'" (R. 626–627).

Upon the basis of the foregoing findings and others subsidiary thereto the Administrator concluded that it would "promote honesty and fair dealing in the interest of consumers" to adopt the standards of identity for farina and enriched farina embodied in Regulations 15.130 and 15.140 (R. 627, 637–638). The Circuit Court of Appeals set aside the regulations on the ground that they exceeded the authority of the Administrator, were unreasonable, and were not supported by substantial evidence.

SPECIFICATION OF ERRORS TO BE URGED

The Circuit Court of Appeals erred:

1. In setting aside Regulations 15.130 and 15.140 of the Federal Security Administrator fixing and establishing definitions and standards of identity for the foods "farina" and "enriched farina."

2. In holding that there was no evidence in support of the Administrator's finding that indiscriminate enrichment of farina with vitamins and minerals would tend to confuse and mislead consumers.

3. In holding that the Administrator is not entitled to consider such tendency to confuse and mislead in reaching the conclusion that it would promote honesty and fair dealing in the interest of consumers to promulgate the regulations under review.

4. In holding that the order was unreasonable in excluding vitamin D from "farina" and permit-

ting it only in "enriched farina," in which vitamin B_1, nicotinic acid and iron, are required.

5. In setting aside the farina and enriched farina standards in their entirety,[5] although petitioner claimed to be adversely affected by the order only insofar as it prohibits the addition to farina of vitamin D unaccompanied by other vitamins and minerals, and did not challenge the regulations in any other respect.

REASONS FOR GRANTING THE WRIT

1. This is the first case to be brought before this Court involving the important food standardization provisions of the Federal Food, Drug, and Cosmetic Act of 1938, and the scope of judicial review of orders of the Federal Security Administrator promulgating food standards.

The Administrator excluded vitamin D from the standard of farina and included it as an optional ingredient in the standard of enriched farina (in

[5] The formal judgment of the Circuit Court of Appeals R. 689) sets aside "the order of the Federal Security Administrator entered on May 26, 1941." Literally this judgment invalidates the standards for flour, enriched flour, bromated flour, enriched bromated flour, durum flour, self-rising flour, enriched self-rising flour, phosphated flour, whole wheat flour, bromated whole wheat flour, whole durum wheat flour, crushed wheat, cracked wheat and semolina, since standards for all of these products were included in the same order in which the farina and enriched farina regulations were also included. However, in the light of the closing two sentences of the opinion (R. 689) it is plain that the order was intended to be limited to "the regulations in controversy."

which other vitamins and minerals are required ingredients) in part upon the basis of independent evidence relating to the desirability of vitamin D and, in part upon evidence establishing that indiscriminate enrichment of farina tends to confuse and mislead consumers and therefore does not "promote honesty and fair dealing in the interest of consumers." The court below, however, set aside the Administrator's standards on the ground that the exclusion of vitamin D from farina and its inclusion in enriched farina as an optional ingredient accompanied by other required ingredients was unreasonable and without substantial support in the evidence and exceeded the Administrator's power. The court below reached this conclusion on the ground that there was no substantial evidence to support the Administrator's finding that indiscriminate enrichment of foods with vitamins and minerals tends to confuse and mislead consumers, and that, in any event, in issuing regulations pursuant to Section 401 of the Act, the Administrator may not consider such tendency to confuse and mislead since it is unrelated to the promotion of honesty and fair dealing in the interest of consumers. In the court's view the concept of the promotion of "honesty and fair dealing" involves only truth in labelling, at least as long as the added ingredients are harmless.

The conclusions of the court below jeopardize the food standards program. Under Section 401 the Administrator has promulgated standards for more

than 150 foods, and standards for numerous other foods are now being formulated. In most of the standards already promulgated, the Administrator has excluded or limited the quantity of one or more ingredients on the ground that their use would not promote honesty and fair dealing in the interest of consumers, although there was no evidence that the proposed ingredients were deleterious or that the proponents of these ingredients intended to misrepresent their products. The decision of the Circuit Court of Appeals in effect invalidates any standard which excludes a non-deleterious ingredient from an accurately labelled food. Thus if the standard of identity for farina must be broad enough to permit Quaker Oats Company to add vitamin D it must likewise permit other manufacturers to add other single vitamins or, indeed, any other nondeleterious substances, provided only that the label discloses the composition of the food. Upon the same principle the standard for enriched farina would have to be broad enough to encompass any nondeleterious variation from the formula specified by the order under review which the producer was willing to disclose by labelling. In short, in the view of the court below, the Administrator is compelled to include in the definition of any food a blanket clause which would permit any manufacturer to add as an additional ingredient any nondeleterious element.

2. The Administrator's finding that indiscriminate enrichment would tend to confuse and mislead

consumers is clearly supported by substantial evidence.

The evidence establishes that there was a wide variation in nutritive supplementation of flour and farina. Thus, the Cream of Wheat Corporation, after extensive investigation, had been supplementing farina with calcium, vitamin B_1, phosphorus and iron (R. 268–269). Pillsbury Flour Mills markets a farina to which only vitamin B_1 is added (R. 609). The Quaker Oats Company was the only manufacturer shown to be adding only vitamin D to farina, and it had varied the quantities added from 121 U. S. P. units per ounce to 1000 U. S. P. units per ounce and most recently to 400 U. S. P. units per ounce (R. 222). In respect of the additional variations in enrichment in flour manufacture * the record shows no less than eight different combinations in vogue (R. 53, 69–70, 75, 118, 130, 161, 197, 562). Yet the whole program of vitamin and mineral enrichment is still in its infancy. The record warrants the conclusion that without controls new "enrichments" will be put forth without scientific or nutritional basis but designed to facilitate exaggerated, if not false, advertising concerning the merits of the new products. For example, one manufacturer of flour admitted in the hearings that he listed vitamin E as a bene-

* The evidence and findings as to enrichment of flour were expressly made applicable to enrichment of farina. See R. 172, 217, 422; Finding 83, R. 626.

ficial element introduced in his product, although need for enrichment of foods with vitamin E has not been established (R. 73; Finding 42, R. 619).

Consumer representatives (R. 116, 488), disinterested scientists (R. 101–103, 104, 409, 413), representatives of affected industries (R. 44, 137), and government food and drug experts (R. 177, 178, 184) testified that indiscriminate enrichment would encourage advertising abuses, and lead to either a general and unwarranted scepticism concerning the enrichment program or to a dangerous credulity. Although the court below rejected this testimony as "speculative and conjectural" (R. 686), the Administrator was plainly entitled to give it weight and was not required to disregard the impressive consensus of this testimony merely because the opinions of necessity dealt with probable future effects of present trends. The terms of Section 401 require the Administrator to make a judgment *in futuro*, namely, that standardization "will promote honesty and fair dealing in the interest of consumers." In improperly equating informed forecast with conjecture, with the result of overturning Findings 36 and 37, the court below ignored the rule of conclusiveness of administrative findings embodied in Section 701 (f) (3) of the Act and in the decisions of this Court. *Consolidated Edison Co.* v. *National Labor Relations Board*, 305 U. S. 197, 229; *National Labor Relations Board* v. *Columbian Co.*, 306 U. S. 292, 299–300.

3. Plainly, therefore, the evidence supported the Administrator's finding that indiscriminate enrichment of foods by multiple variations tends to confuse and mislead consumers. The court below, however, held that in any event consumer confusion was not an element which the Administrator is entitled to consider in fixing standards of food, since in the court's view the elimination of the resulting consumer confusion does not promote honesty and fair dealing in the interest of consumers (R. 686).

But the Administrator was clearly reasonable and justified in concluding that honesty and fair dealing in the interests of consumers are promoted by the elimination of the type of consumer confusion here shown by the evidence to be engendered by the indiscriminate enrichment of foods. Indeed, in so far as such matters are susceptible of evidentiary proof, the very evidence which establishes consumer confusion (*supra*, pp. 13–15) also establishes that such confusion is an obstacle to honesty and fair dealing in the interest of consumers. The program of indiscriminate enrichment gives rise to conflicting and exaggerated claims and encourages advertising abuses (*supra*, p. 15); unable to make an intelligent choice from among the multiple variations clamoring for his purchase, the consumer is a ready victim of conflicting and unwarranted claims. The ill-advised skeptic will pay as much for plain farina as for the superior product, enriched farina (cf. R. 413); the credulous can be persuaded to pay as much for one vitamin as for

four (cf. R. 177). There can, in these circumstances, be small assurance that the consumer will be able to select the foods which are, in fact, what he wishes. Consumer confusion created by indiscriminate enrichment, therefore, has an immediate bearing upon the promotion of honesty and fair dealing in the interest of consumers, and not, as the court below thought, exclusively upon public health (R. 684). And plainly the prevention of such potentialities of unfair dealing, arising from the consumer's confusion, is a legitimate objective under the Food, Drug and Cosmetic Act. Cf. *Federal Trade Commission* v. *Raladam Co.*, 316 U. S. 149, 152. This being so, it was for the Administrator, not the court, to determine, within the limits of reasonableness, the reach of the regulation in order to eliminate the confusion. In holding that label disclosure of ingredients is a better guaranty against confusion and deception of consumers than the standardization ordered by the Administrator, the court below disregarded the principle, long since established by this Court, that it is for the administrative agency and not the reviewing court to say whether accurate labelling of a food constitutes sufficient protection against deception of consumers.[1] *Houston* v. *St. Louis Packing Co.*,

[1] The Circuit Court of Appeals misconceived the argument relative to confusion when it stated that sale of Quaker's farina, accurately labelled as to ingredients, would confuse consumers less than sale of standardized enriched farina which need not, under Section 403 (g), be labelled to disclose required ingredients. The Government did not contend

249 U. S. 479, 484; cf. *United States* v. *Carolene Products Co.*, 304 U. S. 144.

4. Apart from the evidence that indiscriminate enrichment of foods by such ingredients as vitamin D creates consumer confusion other evidence also supports the exclusion of vitamin D from the definition of farina. Thus, the evidence establishes that persons deficient in one vitamin are likely to be deficient in several (R. 287). One physician stated, "It is practically impossible to find a single dietary deficiency in clinical practice * * *" (R. 366). Similarly, a nutrition expert, testifying on behalf of respondent, endorsed the principle of multiple enrichment (R. 95, 220–221). Further, the record shows that the American Medical Association and the Bureau of Home Economics, Department of Agriculture, were opposed to the use of vitamin D in flour and farina (R. 102–103, 497).[8] In these circumstances it was plainly reasonable

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that the sale of any particular product would be confusing or misleading, but only that an unrestricted diversity of products, even though honestly labelled, will tend to confuse and mislead consumers.

[8] This opposition was presumably based upon the considerations that vitamin D is not present in significant quantities in whole wheat and is therefore not one of the substances lost by over-refinement (R. 91, 116, 298); that the primary function of vitamin D is to facilitate the absorption of calcium, a mineral which is found in dairy foods and not in cereals (R. 79, 81, 83, 104, 298, 367); and that it is not established that adults are deficient in vitamin D (R. 368, 390).

There was clearly no basis for holding the regulations unreasonable on the ground that they will "deprive" many consumers of vitamin D, or at least prevent the consumer

for the Administrator to exclude vitamin D from farina while permitting it as an optional ingredient in enriched farina where it appears in combination with other required enriching elements.

It is evident that in holding the regulations unreasonable the court below substituted its own judgment for that of the Administrator "in a domain of knowledge still shifting and growing, and in a field where judgment is therefore necessarily beset by the necessity of inferences bordering on conjecture even for those learned in the art." *Railroad Commission* v. *Oil Co.*, 310 U. S. 573, 581; *National Labor Relations Board* v. *Link-Belt Co.*, 311 U. S. 584, 596–597; *Gray* v. *Powell*, 314 U. S. 402, 412.

CONCLUSION

For the foregoing reasons it is respectfully submitted that this petition for a writ of certiorari should be granted.

CHARLES FAHY,
Solicitor General.

SEPTEMBER 1942.

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from obtaining vitamin D in farina unless he buys enriched farina (R. 687). As the record shows, the consumer who requires D is likely to require other vitamins as well; in any event he will not suffer any disadvantage from the extra nutrients in enriched farina: There is no showing that enriched farina with vitamin D added would not be readily available at no appreciable extra cost or that vitamin D will not otherwise be obtainable.

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No. 424

In the Supreme Court of the United States

OCTOBER TERM, 1942

FEDERAL SECURITY ADMINISTRATOR, PETITIONER

v.

THE QUAKER OATS COMPANY

ON WRIT OF CERTIORARI TO THE UNITED STATES CIRCUIT COURT OF APPEALS FOR THE SEVENTH CIRCUIT

BRIEF FOR THE FEDERAL SECURITY ADMINISTRATOR

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BRIEF FOR THE FEDERAL SECURITY ADMINISTRATOR

OPINION BELOW

The opinion of the Circuit Court of Appeals (R. 679–689) is reported in 129 F. (2d) 76. The Findings of Fact of the Federal Security Administrator appear as part of his Final Order at R. 610–627. The Administrator's regulations concerning "farina" and "enriched farina," also part of his Final Order, appear at R. 637–638.

JURISDICTION

The judgment of the Circuit Court of Appeals was entered June 26, 1942 (R. 689). The petition

for a writ of certiorari was filed on September 26, 1942, and was granted November 9, 1942. The jurisdiction of this Court rests on Section 240 (a) of the Judicial Code, as amended by the Act of February 13, 1925, and Section 701 (f) (4) of the Federal Food, Drug, and Cosmetic Act of June 25, 1938, 52 Stat. 1040, 1055, 21 U. S .C., Sec. 371.

QUESTIONS PRESENTED

The ultimate question presented is whether regulations 15.130 and 15.140 of the Federal Security Administrator, excluding vitamin D from the definition and standard of identity for "farina" and permitting it only in "enriched farina" in which vitamin B_1, riboflavin, nicotinic acid, and iron are required, are valid. This question depends in turn upon the subsidiary questions:

(a) whether there is substantial evidence in support of the Federal Security Administrator's finding that indiscriminate enrichment of farina with vitamin and mineral supplements would tend to confuse and mislead consumers;

(b) whether, if so, the Administrator has statutory authority, upon finding the existence of such a tendency, to promulgate a standard of identity which excludes disclosed, non-deleterious ingredients, in order to promote honesty and fair dealing in the interest of consumers;

(c) whether the Administrator's treatment of vitamin D is reasonable.

STATUTE INVOLVED

The Federal Food, Drug, and Cosmetic Act of 1938, 52 Stat. 1040, 1046, 1055 (21 U. S. C., Secs. 341 and 371), in pertinent part, provides as follows:

> SEC. 401. Whenever in the judgment of the Administrator [1] such action will promote honesty and fair dealing in the interest of consumers, he shall promulgate regulations fixing and establishing for any food, under its common or usual name so far as practicable, a reasonable definition and standard of identity, a reasonable standard of quality, and/or reasonable standards of fill of container * * *. In prescribing a definition and standard of identity for any food or class of food in which optional ingredients are permitted, the Administrator shall, for the purpose of promoting honesty and fair dealing in the interest of consumers, designate the optional ingredients which shall be named on the label. * * *
>
> * * * * * *
>
> SEC. 701 (e). The Administrator, on his own initiative or upon an application of any interested industry or substantial portion thereof stating reasonable grounds therefor,

[1] The terms "Federal Security Administrator" and "Administrator" have been substituted for the actual language "Secretary of Agriculture" and "Secretary" because by Reorganization Plan No. IV, 54 Stat. 1234, the Federal Food and Drug Administration and its functions were transferred to the Federal Security Agency and the functions of the Secretary of Agriculture relating to the administration of the Act were transferred so as to be exercised by the Federal Security Administrator.

shall hold a public hearing upon a proposal to issue, amend, or repeal any regulation contemplated by any of the following sections of the Act: 401. * * * At the hearing any interested person may be heard in person or by his representative. As soon as practicable after completion of the hearing, the Administrator shall by order make public his action in issuing, amending, or repealing the regulation or determining not to take such action. The Administrator shall base his order only on substantial evidence of record at the hearing and shall set forth as part of the order detailed findings of fact on which the order is based.

SEC. 701 (f) (1). In a case of actual controversy as to the validity of any order under subsection (e), any person who will be adversely affected by such order if placed in effect may * * * file a petition with the Circuit Court of Appeals of the United States for the circuit wherein such person resides or has his principal place of business, for a judicial review of such order * * *.

* * * * *

SEC. 701 (f). (3). The court shall have jurisdiction to affirm the order, or to set it aside in whole or in part, temporarily or permanently * * *. The findings of the Administrator as to the facts, if supported by substantial evidence, shall be conclusive.

STATEMENT

On May 26, 1941, after notice and hearing under Section 701 (e) of the Act, the Acting Federal

Security Administrator promulgated a Final Order containing regulations fixing and establishing definitions and standards of identity for sixteen milled wheat products, including "farina" and "enriched farina" (R. 628–639). Regulation 15.130 defines farina as the food prepared by grinding and bolting cleaned wheat other than durum wheat and red durum wheat to a prescribed fineness, with bran coat and germ removed to a prescribed extent (R. 637). There is no provision for optional ingredients in farina. Regulation 15.140 defines enriched farina as farina conforming to Regulation 15.130 but containing in addition prescribed minimum quantities of vitamin B_1, riboflavin,[2] nicotinic acid, and iron; enriched farina may also, but is not required to, contain vitamin D, calcium, wheat germ, or disodium phosphate as optional ingredients (R. 637–639).

Respondent, The Quaker Oats Company, has since 1932 manufactured and marketed a product consisting of farina plus vitamin D, under the package label "Quaker Farina Wheat Cereal Enriched with Vitamin D" or "Quaker Farina Enriched by the Sunshine Vitamin" (R. 218, 640). The back panel label of the package bears the legend, "Contains 400 U. S. P. Units of Vitamin D per ounce supplied by approximately the addition

[2] Largely because of the effects of war priorities and lend-lease requirements the effective date of the riboflavin provision has been postponed until April 20, 1943 (7 Fed. Reg., p. 3055, April 25, 1942).

of ½ of 1 percent irradiated dry yeast" (R. 218). Upon the issuance of the Administrator's Final Order, respondent filed a petition for judicial review in the court below (R. 640–644) alleging that the effect of the standards for farina and enriched farina is to require it either to cease adding vitamin D or to include in any farina which "purports to be or is represented as" enriched farina the prescribed minimum quantities of vitamin B_1, nicotinic acid, and iron, in addition to the vitamin D which it now uses.[4] The petition further alleged that the regulations were invalid upon the grounds, *inter alia*, that they were unreasonable, not based upon substantial evidence, and beyond the statutory authority conferred upon the Administrator.

The Administrator's findings relating to vitamin and mineral enrichment of flour[5] and farina (R. 617–619, 624–627) may be summarized as follows:

Flour is a principal item of the American dietary particularly among low-income groups (R. 617).

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[4] This allegation was not denied and was conceded by the Administrator in the court below. This result flows from the application of Section 403 (g).

[5] The findings with respect to enrichment of flour are incorporated by reference into the farina findings. Finding 83, R. 628. This recognizes the witnesses' treatment of the separate enrichment problems in each food as merely phases of the general problem of enrichment. See e. g., R. 89–105, 116, 165, 184. Although the respondent disputed below the relevance of the evidence and findings of flour enrichment to farina enrichment, the court below recognized the relationship between the two. R. 681. See the request by respondent's representative that his and all other enrichment testimony on flour be made applicable to farina, R. 217.

Farina is not as widely consumed as flour, but is used in macaroni products and as a breakfast food. It is extensively used as a cereal food for children and in many cases is the only cereal fed to children during a period of their growth (R. 626).

Farina and flour are both manufactured by grinding whole wheat and separating off the bran coat and germ, the finished product consisting almost entirely of the remaining portion of the wheat known as endosperm (R. 611, 625). The process of milling off the bran and germ removes those portions which are richest in vitamins and minerals (R. 626). The original whole wheat is rich in vitamin B_1, riboflavin, nicotinic acid, and iron, which are lacking in many diets, particularly among low-income groups (R. 617, 618). Deficiencies of calcium also exist. Vitamin D deficiency is widespread among infants and children, but calcium and vitamin D are not listed among the elements present in wheat in substantial quantities (R. 617, 618).

Millers have recently placed on the market flours and farinas which have been "enriched" by the addition of various vitamins and minerals (R. 617–618, 626). The composition of these enriched products, however, varies widely and unless a standard of identity is adopted which limits the kinds and amounts of enrichment, "the manufacturers' selection of the various nutritive elements and combinations of elements on the basis of economic and

merchandising considerations is likely to lead to a great increase in the diversity, both qualitative and quantitative, in enriched flour offered to the public. Such diversity would tend to confuse and mislead consumers as to the relative value of and need for the several nutritional elements, and would impede rather than promote honesty and fair dealing in the interest of consumers". (R. 618.) Indiscriminate enrichment "would tend to confuse and mislead consumers by giving rise to conflicting claims regarding the beneficial effects" of the added ingredients "and would be likely to lead to the impression on the part of consumers that a single article of food so enriched would meet all nutritional needs." On the other hand, limited enrichment "is readily adapted to the promotion of consumer understanding of the relative value of enriched and natural foods". (R. 618.)

Upon the basis of the foregoing findings and other subsidiary findings, the Administrator concluded that it would "promote honesty and fair dealing in the interest of consumers" to adopt the standards of identity for farina and enriched farina embodied in Regulations 15.130 and 15.140 (R. 627, 637–638).

The court below set aside the regulations on the ground that the findings relating to consumer confusion were not supported by substantial evidence, and that the regulations exceeded the authority of the Administrator and were unreasonable (R. 679–689).

SPECIFICATION OF ERRORS TO BE URGED

The Circuit Court of Appeals erred:

1. In setting aside Regulations 15.130 and 15.140 of the Federal Security Administrator fixing and establishing definitions and standards of identity for the foods "farina" and "enriched farina."

2. In holding that there was no evidence in support of the Administrator's finding that indiscriminate enrichment of farina with vitamins and minerals would tend to confuse and mislead consumers.

3. In holding that the Administrator was not entitled to consider such tendency to confuse and mislead in reaching the conclusion that it would promote honesty and fair dealing in the interest of consumers to promulgate the regulations under review.

4. In holding that the order was unreasonable in excluding vitamin D from "farina" and permitting it only in "enriched farina," in which vitamin B_1, riboflavin, nicotinic acid, and iron are required.

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* The court below also erred in setting aside all the wheat products standards in their entirety, although petitioner claimed to be adversely affected by the order only insofar as the farina and enriched farina standards prohibit the addition to farina of vitamin D unaccompanied by other vitamins and minerals, and did not challenge the regulations in any other respect. The formal judgment of the Circuit Court of Appeals (R. 689) sets aside "the order of the Federal Security Administrator entered on May 26, 1941." Literally this judgment invalidates the standards for flour, enriched flour, bromated flour, enriched bromated flour, durum

SUMMARY OF ARGUMENT

A. The Administrator's finding that indiscriminate enrichment of wheat products would confuse and mislead consumers is supported by substantial evidence. The science of vitamin nutrition is in its infancy; its terminology is new and difficult; and consumer comprehension of its limitations and prospects is rudimentary. These facts, coupled with the possibilities of relief from various diseases offered by this new science, make the field peculiarly susceptible to exploitation on the basis of half-truths and partial enrichments which will not fulfill the consumer's reasonable expectation of substantial contribution to his dietary requirements by "enriched" foods.

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flour, self-rising flour, enriched self-rising flour, phosphated flour, whole wheat flour, bromated whole wheat flour, whole durum wheat flour, crushed wheat, cracked wheat, and semolina, since standards for all of these products were included in the same order in which the farina and enriched farina regulations were also included. There was no controversy concerning these standards, and indeed, respondent has no such interest in them as would entitle it to judicial review of them. Further, the judgment on its face invalidates phases of the farina and enriched farina regulations, such as fineness of grind of farina and the option for disodium phosphate in enriched farina, about which respondent did not complain in its petition for review (R. 640-644). Since the court below accepted all findings of fact except those on the confusing and misleading of consumers (R. 681, 683), and its opinion concludes by holding that the "regulations in controversy" must be set aside (R. 689), the broad form of the actual judgment appears to be inadvertent and will not be argued herein. Plainly, the court's order went far beyond the scope of respondent's attack upon the regulations and beyond the issues which were before it.

The record shows a wide range of variation in existing manufacturing practice with regard to enrichment, both in the selection and quantities of vitamins and minerals added. Consumer representatives, scientists, industry technicians and government food and drug experts all testified that continuation of such indiscriminate enrichment would confuse and mislead consumers. The Administrator was plainly entitled to give weight to this expert testimony concerning the probable effect of present trends. The testimony cannot be dismissed simply because it is in part cast in terms of the future. In the issuance of regulations, it is normally necessary to make a judgment *in futuro;* the testimony which furnishes a basis for such a judgment does not thereby become "speculation" and "conjecture."

B. The likelihood that consumers will be confused and misled by unrestricted variation in nutritive supplementation of food justifies the promulgation of standards of identity which will bar some of the variants even though wholesome and accurately labelled. The history of administrative standards and of food and drug legislation prior to and including the Federal Food, Drug, and Cosmetic Act of 1938 makes it clear that Congress contemplated regulations under Section 401 which, in the interests of standardization, might prevent interstate traffic in wholesome nonfraudulent foods. The earliest food standards issued at the beginning

of this century by the Department of Agriculture excluded from the standardized articles all substances not mentioned in the definitions, without regard to the wholesomeness of the ingredients excluded. When Congress itself enacted a standard of identity for butter in the Butter Standard Act of 1923 it plainly evinced its intention to restrict the composition of butter to the ingredients named in the statute. The Food, Drug, and Cosmetic Act of 1938 carefully distinguishes between standards of identity which are intended to guarantee the "integrity of food products" and standards of quality where specific provision is made for sale of substandard articles under an informative label. The phrase "promote honesty and fair dealing," as used in Section 401, does not restrict identity standards to mere prohibitions of false labelling. On the contrary, the phrase is wholly consistent with exclusion of harmless ingredients, especially where, as here, the basis of consumer confusion is the existence of multiple variations. *Pacific States Box Co.* v. *White*, 296 U. S. 176, 181–182. And it is established that the test of preventing deception resulting from variations does not limit administrative authority to a requirement of label disclosure. *Houston* v. *St. Louis Independent Packing Co.*, 249 U. S. 479, 484; cf. *United States* v. *95 Barrels Cider Vinegar*, 265 U. S. 438, 445.

C. If, as we submit, standards of identity may exclude harmless and disclosed ingredients, the only issue is whether the particular line drawn by the

Administrator is reasonable, not whether he may reasonably have drawn a different line. There was a reasonable basis for the Administrator's exclusion of vitamin D from the farina standard and for his requirement that enriched farina, in which vitamin D is permitted, must contain four other nutrients. The evidence shows that the four required ingredients of enriched farina are of great importance to the diet and that their deficiencies are widespread. It shows further that these four ingredients are originally contained in the whole wheat berry, and are naturally related to it, while vitamin D is not contained in the berry in appreciable quantities. The standards, therefore, are an accommodation to existing natural, dietary and historical phenomena, and are reasonable.

ARGUMENT

THE COURT BELOW ERRED IN SETTING ASIDE THE ADMINISTRATOR'S REGULATIONS SINCE THE FINDINGS WERE SUPPORTED BY SUBSTANTIAL EVIDENCE AND THE REGULATIONS WERE AUTHORIZED BY THE ACT AND WERE REASONABLE

Introductory.—Section 401 of the Federal Food, Drug, and Cosmetic Act of 1938 authorizes the Administrator to promulgate regulations fixing reasonable standards of identity for foods whenever in his judgment "such action will promote honesty and fair dealing in the interest of consumers." Finding that indiscriminate enrichment of farina with vitamins and minerals would tend to confuse

and mislead consumers and would impede rather than promote honesty and fair dealing in the interest of consumers, the Administrator issued regulations which fixed the standards of identity for "farina" and for "enriched farina."

The instant controversy arises from the Administrator's failure to include vitamin D as an ingredient in farina, and from his requirement that enriched farina, in which vitamin D is permitted, must include four other factors—vitamin B_1, riboflavin, nicotinic acid, and iron. Respondent, The Quaker Oats Company, has for a number of years manufactured and marketed a product which consists of farina plus vitamin D. Its position is that the regulations, to be valid, must provide that vitamin D may be added to farina and that since the farina standard does not permit this, while the enriched farina standard permits vitamin D only in combination with the other factors, both standards are void. Respondent's attack in the court below was grounded upon its allegations that the Administrator's findings were without substantial support in the evidence; that, under the Act's test of promotion of "honesty and fair dealing in the interest of consumers," the Administrator's authority extends only to the exclusion in his regulations of ingredients which are deleterious or undisclosed; and that his treatment of vitamin D was unreasonable. It is contended that the Administrator cannot take into considera-

tion the consumer confusion which inheres in multiple farina products with varying additions of vitamins and minerals; his discretion is at an end once he determnes that a factor is wholesome, for upon such determination, he must so shape his regulation as to permit the inclusion of that factor.

The court below agreed with respondent's contentions. The finding upon which the Administrator's determination initially hinges—that indiscriminate enrichment of these products tends to mislead and confuse consumers and that, accordingly, standards which exclude the enrichment (in the case of farina) or limit it to a *cluster* of factors (in the case of enriched farina) would promote honesty and fair dealing in the interest of consumers—was rejected as without substantial support. The court below held that harmless ingredients could not be excluded from a correctly labeled food and that, in any event, the tendency to mislead and confuse which the Administrator found to exist is not an element which he may consider since it is unrelated to the promotion of honesty and fair dealing in the interest of consumers. The requirement of honesty and fair dealing, in the court's view, is satisfied by truthful labe[illegible] at least as long as the variations are additional ingredients which are harmless. The regulations, therefore, must be sufficiently broad to permit a manufacturer to include any wholesome ingredient; if they do not, they are unauthorized and unreasonable.

It is our position, however, that the record supports, and the Act permits, the regulations under review, and that they are reasonable. The validity of the regulation turns at the outset upon the question whether the Administrator's finding, rejected by the court below, that indiscriminate enrichment would tend to confuse and mislead consumers, is supported by substantial evidence as required by Section 701 (f) (3) of the Act. We shall show in Point A that it is so supported both by the general evidence relating to enrichment and by specific expert testimony concerning the consequences of indiscriminate enrichment in this field. Second, the validity of the regulations turns upon whether the findings furnish a legal basis for the regulation. This depends on the question whether the Administrator, under the Congressional requirement embodied in Section 401, that his action promote "honesty and fair dealing" is entitled to consider the existence of a tendency to confuse and mislead consumers stemming from a multiplicity of products enriched in varying ways, or whether, on the other hand, such confusion is irrelevant under the Act and the requirement of honesty and fair dealing is satisfied by truthful labeling, so that the Administrator is without power to exclude nondeleterious ingredients from his definitions. We shall show in Point B that the Administrator's action in considering the evidence establishing confusion and misleading of consumers is consistent with and authorized by, the terms and the history

of the Act, and with the course of judicial decisions. In Point C, we shall show that the Administrator's treatment of vitamin D—excluding it from farina, and permitting its inclusion in enriched farina only in combination with other elements—is reasonable.

A. The Administrator's finding that indiscriminate enrichment of farina would tend to confuse and mislead consumers is supported by substantial evidence.

The Administrator is authorized by Section 401 of the Act to issue reasonable standards of identity for foods where in his judgment such action will promote honesty and fair dealing in the interest of consumers. A situation must, therefore, exist which in the Administrator's judgment warrants his action. The Administrator found that such a situation did exist, arising from the practice of indiscriminate enrichment of flour and farina which tended to confuse and mislead consumers. We submit that the court below was in error in holding that this basic finding was without substantial evidentiary support. Such support rests upon both the general testimony relating to the problem of food enrichment which itself gives rise to the inference that indiscriminate enrichment tends to confuse and mislead consumers, and upon direct expert testimony that such a tendency to confuse and mislead does in fact exist.

1. The problem with which the Administrator was faced in promulgating the instant standards

has its roots in the development of knowledge of vitamins and mineral factors. Research,—since widely publicized,—in the science of nutrition, principally within the present century, has discovered the importance of vitamin and mineral ingredients in diet, and the unhealthful effects of deficiencies of these ingredients.

While scientific knowledge in this field is not yet complete and certain, the importance of the vitamin and mineral ingredients which the Administrator included as required or optional in his standard of enriched farina is well established. Deficiency of vitamin B_1,[6] the first of the four ingredients required by the enriched farina standard, is the most widespread (R. 290–291, 411, 435): it is the cause of beriberi, and in less severe cases results in abnormal susceptibility to fatigue, nervous disorders, rheumatism, loss of appetite, or gastro-intestinal disorders (R. 51–52, 57–58, 108, 387, 408, 414).[7] Deficiency of riboflavin,[8] the second ingre-

[6] Vitamin B_1 is sometimes known as thiamin or thiamin chloride (R. 49, 380–381).

[7] This was the one vitamin universally recommended as proper for addition to wheat products and favored by most witnesses, including those representing the industry, as the one which should be a required ingredient (R. 263, 435, 442, 446, 475). The National Research Council has recommended B_1 for inclusion in our army specifications (R. 106), and in England there is a legal requirement that B_1 and calcium be added to flour (R. 46, 65, 129).

[8] Riboflavin is sometimes known as vitamin B_2 or G (R. 186).

dient required by the enriched farina standard, leads to abnormal susceptibility to fatigue and to vision disturbances (R. 108, 127). Deficiency of nicotinic acid,[9] the third required ingredient,[10] is the cause of pellagra (R. 51, 121, 369, 387–388). Iron, the fourth ingredient required by the enriched farina standard, is a red blood cell constituent, deficiency of which leads to anemia (R. 272–274, 284). Calcium, which is an optional ingredient included in enriched farina, has an important bone-building function; its deficiency causes rickets in children and other bone diseases in older people (R. 103, 272). Vitamin D, another optional ingredient and the only one which respondent adds to its farina, is important for the utilization of calcium, and vitamin D deficiency therefore may lead to the same results as calcium deficiency (R. 78, 81, 85, 103, 235).[11]

[9] Nicotinic acid is sometimes known as the antipellagra, or pellagra preventive factor (R. 64, 187, 379, 492).

[10] All three ingredients, plus certain other vitamins (but not including vitamin D) are sometimes referred to as the vitamin B complex (R. 108).

[11] Two additional optional ingredients are also allowed by the enriched farina standard. One, disodium phosphate, has no substantial nutritional significance, but is permitted because it facilitates quick cooking (R. 269; Finding 85, R. 626). The other, wheat germ, is nutritionally significant as a supplier of all four of the required factors of the standard, and is permitted in limited amounts because it may be less costly than artificial additions since it is itself a flour mill byproduct, and because it is a convenient carrier of artificial additions (R. 52, 57, 527; Finding 44, R. 619; Finding 82, R. 626).

Other nutritional elements, particularly vitamins A, B_6, C, and E, pantothenic acid, and phosphorus, were recom-

In addition, the evidence establishes the natural relationship to the basic farina product of the four factors which the Administrator's standard required as ingredients of enriched farina. The original whole wheat berry, the ultimate source of farina products, is rich in these four factors (B_1, riboflavin, nicotinic acid, and iron) (R. 120, 127–128), but a relatively poor source of the optional added enrichments (calcium and vitamin D) (R. 78–80, 144, 286, 298). In respect of these, milk is the ideal calcium source, while vitamin D, whose "natural" source is sunlight, is found in significant quantities only in cod liver and certain other fish oils (R. 79–80, 87, 91).

Although whole wheat is thus an excellent source of the four required factors of the enriched farina standard, contribution of these factors to the American dietary has been substantially decreasing in the last fifty years. This is due to an evolution both in dietary habits and in the process of manufacture. The per capita consumption of wheat has dropped by two-fifths since 1900, to a present average consumption of only one-fourth to one-third of the total caloric requirement, while the

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mended by witnesses as additional enrichments (R. 69, 73, 95–96, 439), but were not included either as required or optional. The state of knowledge as to the effects of vitamin E is limited, and as to vitamin A and C, it is known that even if naturally present or inserted into wheat products they would be largely destroyed by the cooking or baking process (R. 108–109, 120, 148, 185, 384, 413. Findings 41, 42, R. 619).

consumption of sugar, which contains neither vitamins nor minerals in significant quantities, has risen (R. 119, 183, 191, 247, 312, 367, 401, 416). In addition changing milling processes, developed in response to public demand for fine white products, have milled off the bran and germ, which are the principal vitamin and mineral-bearing constituents of the wheat berry. As a result there remain in flour and farina primarily the endosperm, the starchy portion of the berry which is leanest in these constituents." (R. 100–102, 118, 127, 276, 325–341, 525.) This abstraction of vitamin and mineral constituents from the wheat berry is particularly marked in the case of farina, which corresponds to a grade of flour known as "patent flour" and is almost entirely free of bran coat and germ (R. 206, 212–213, 625). As a result of the severe milling process to which farina is thus subjected, it has less than a tenth of the B[1] content of whole wheat, only a quarter of its riboflavin content; only two-thirds of its iron content; and there is also some reduction in nicotinic acid content[2] (R. 127–128, 272, 275–276, 278–279, 412).

These facts have led to the efforts of producers of flour and farina to compensate for the loss of important ingredients. There has been considerable

[1] See diagram of wheat kernel (R. 523).

[2] The amount of the nicotinic acid reduction is not stated. The record shows that techniques of measurement of nicotinic acid have not been perfected (R. 121, 361).

public knowledge of the deficiencies of flour and farina, and as a result consumers have "been more or less frightened away from the consumption of cereals" (R. 312). To counteract this the milling industry has in recent years been adding either natural or synthetic vitamin and mineral values to the milled products and has been engaged in commercial exploitation of these products as "enriched," "fortified," or "restored" (R. 107, 118, 128–130, 153–154, 231).

But these additions have taken place indiscriminately and with wide individual variations. Among flours, there was testimony concerning no less than six variations in nutritional [1] additions contained in existing products on the market. To one flour is added vitamin B_1, nicotinic acid, and calcium—a formula used by more than twenty mills (R. 46–47); to a second is added vitamin B_1, riboflavin, calcium and iron (R. 130); a third has added vitamin B_1, riboflavin, vitamin E and unspecified minerals (R. 73; cf. R. 276); a fourth includes vitamin B_1, calcium and iron (R. 161); to a fifth calcium is added (R. 197–199); and to a sixth, vitamin D is added (R. 75–77). A like variation in nutritional

[1] The constituents here enumerated are only those added for the purpose of supplying nutritional deficiencies. Incidental additions, such as the other mineral concomitants of the compounds used to add calcium and iron (R. 270, 272, 360, 440), and minerals added for special nonnutritional purposes such as quick-cooking and self-rising features, are omitted (R. 199–200, 263, 299).

additions exists" in the more limited field of farinas: Two farinas (including respondent's farina) (R. 77, 503) contain vitamin D; two or three add vitamin B_1 plus minerals (R. 268, 504); and two add vitamin B_1 (R. 503). And, as the Administrator found (R. 618), existing various represents only the beginning of a process of differentiation which will result in "a great increase in the diversity" (R. 118, 138, 161).

The effects upon consumers in their selection among the variously enriched foods, and their inability to make an informed choice, was expressly described by expert witnesses. Consumer representatives (R. 116, 165–171, 173–175, 488), disinterested scientists (R. 101–103, 104, 409), industry representatives (R. 147, 311–312), and federal food and drug experts (R. 177–178, 184) all testified that indiscriminate enrichment confuses and misleads consumers because of their inadequate knowledge of the nomenclatures and functions of the several vitamins and minerals involved in dietary deficiency; or that a minimum uniformity in the content of the enriched product was necessary to assure the consumer, buying on the assumption of dietary efficacy, that there would be such efficacy.

Thus a scientist who is a pioneer in vitamin research and education (R. 407) testified (R. 413)

[10] The farina information comes from two sources which may overlap in part, a mill survey tabulation exhibit, and the direct testimony (R. 24–28, 503–504); hence the alternate numbers given for certain types of farinas.

that "* * * if there is a great diversity of products sold under a great diversity of names and with a great diversity of formulas, then the public is going to be merely confused by the changes". A witness from the Bureau of Home Economics of the Department of Agriculture, reporting the joint views of a group of nutritionists in the Bureau who are engaged in advising consumers on food selection problems (R. 175–176), testified (R. 177):

> Any standard for white flour that allows the optional addition of one or a dozen of these nutrients would not promote honesty and fair dealing in the interests of the consumer. Such a standard would tend to confuse consumers and the fortified product might seem to them to be a short cut to a balanced diet. * * * Most nutritionists would oppose creating a standard for a multiplicity of kinds of supplemented flours, each of which was unstandardized and independent of all the rest. It would lead to advertising abuses; advertising claims would tend to be accepted too credulously by some and rather completely discounted by others. * * *."[6]

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[6] Compare the testimony of two consumer witnesses who emphasized the importance of some assurance to the consumer that a definite expectation of nutritional value will be fulfilled:

"* * * an identity or definition for flour should describe it and limit it in such a way that you can always depend on being able to use it for the purpose that you have in mind."

Underlying such testimony against optional indiscriminate variation as failing to comport with what the consumer "will know" (R. 147) or will "recognize" (R. 177), or with what is necessary as "a guide in buying" (R. 170), or "being able to use it for the purpose that you have in mind" (R. 174) is the judgment concerning the consumer's ability to discriminate and the inadequacy of label disclosure as a guide for discrimination. This judgment is particularly explicit in the testimony of two of the witnesses, both of them professionally in contact with consumer reactions. Thus a member of the technical staff of Consumers Union of the United States, a nonprofit testing and information organization serving 80,000 consumer members (R. 487–488), endorsed the principle

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"Now, the difficulty with getting a wide proposal would be that if you could have flour without additional calcium and vitamins and so on, it will behave one way in feeding your family, and if you can have flour that may have vitamins and no calcium, it will do something else, and if you can have flour that will supply maybe as much as half of the calcium you need, and no vitamins it is very different still, so that you get many different products." (R. 174–175.)

"We realize that if standards are set limitations are put on, that certain flour will be excluded, and of course as consumers we do not want arbitrary definitions that make the price of the commodity go up considerably, yet we recognize that definitions have to be exclusive or else they are no good at all, * * *.

"All that the consumer can say to help guide you in this decision is that we feel that the definition should not be broadened, because it would make the standard of identity of less value to us as a guide in buying." (R. 170; see also passim, R. 165–171.)

embodied in the enriched farina standard, i. e., required multiple enrichment at least to whole wheat levels under a single name, but with optional added ingredients including vitamin D (R. 489–490, 496), stressing the danger that anything less "tends to cause a false sense of security when it is coupled as it so frequently is, with rather dubious advertising claims" (R. 488). This witness emphasized the state of partial public digestion of scientific information on nutrition; she testified that (R. 492) "the average consumer is in a truly difficult position. He is just beginning to learn one set of names, and tying them up with functions and requirements. All possible efforts should we feel be made to keep his job as easy as possible." [17]

This evidence relating both to the facts of enrichment and to the resulting tendency to confuse and mislead consumers furnished substantial support to the Administrator's findings (R. 617–618) that such a tendency exists. Although the court below rejected this testimony as "speculative and conjectural" (R. 686), the Administrator was plainly entitled to give it weight. In so far as the testi-

[17] See also the testimony of Dr. Robert S. Harris that (R. 311):

"* * * I believe that we are trying to apprise the consumer thinking the consumer is a home economist, or someone of that training, and not thinking of the consumer as being a person of rather poor education, of little realization of all of these nutritional things, and by telling how many units there are or perhaps even what proportion those units are of the day's requirements, I am afraid that lots of people that I know will miss the point; * * *."

mony summarized above related to ascertainable facts—the fact of the existence of a multiplicity of enrichments, the fact of general consumer ignorance of the kinds, quantities and combinations of nutrients which he should find in foods, the fact of advertising claims based upon the varying additions—there was no element of speculation or conjecture. These facts alone posed the problem and reasonably supported the inference, which was within the Administrator's special administrative competence to draw, that consumers would be confused and misled by indiscriminate enrichment.

Nor was the Administrator required to disregard the impressive consensus of the testimony directly establishing the tendency toward confusion and misleading of consumers merely because the opinions of necessity dealt with probable future effects of present trends. Whatever the admissibility and probative value of such testimony in administrative *adjudicatory* proceedings which deal with ascertainment of past facts, evidence of this nature is clearly competent in administrative *rule-making* proceedings.[18] Cf. *Final Report of*

[18] Respondent did not object to this testimony and did not except to the Administrator's proposed findings relating to confusion, although it was identical to the final findings here under review (R. 575–576, 598–604, 618). Thus, in any event, respondent would seem to be foreclosed from pressing objections to this evidence at this stage. *Opp Cotton Mills v. Administrator*, 312 U. S. 126, 155; *Spiller v. Atchison, T. & S. F. Ry.*, 253 U. S. 117, 130; *Rowland v. St. Louis and S. F. R. Co.*, 244 U. S. 106, 108.

the Attorney General's Committee on Administrative Procedure, Sen. Doc. No. 8, 77th Cong, 1st sess., p. 109. Rule-making is the administrative performance of legislative functions and operates *in futuro.* The terms of Section 401 expressly require the Administrator to make a judgment *in futuro,* that standardization *"will"* promote honesty and fair dealing in the interest of consumers; plainly the testimony of these witnesses which the court below rejected is the very type upon which legislators are accustomed to rely in legislative hearings. At least in rule making, therefore, the evidence meets the test of possessing "rational probative force." Cf. *Consolidated Edison Co.* v. *National Labor Relations Board,* 305 U. S. 197, 229-230.

Nor is the absence of proof that the respondent's product has in itself been in the past the subject of "deception, fraud, or misrepresentation of any kind" fatal, as the court below thought (R. 683), to the Administrator's finding that indiscriminate enrichment would confuse and mislead. The purport of this finding is not that individual manufacturers have been perpetrating common law frauds, but that the total effect of many manufacturers engaging in indiscriminate partial enrichments would be confusing and misleading whatever the honesty of each manufacturer be. Even in *Federal Trade Commission* v. *Raladam Co.,* 283 U. S. 643, cited by the court below as supporting its view that the instant findings as to confusion were mere specula-

tion and conjecture (R. 686), this Court, in pointing out that the Federal Trade Act required proof rather than conjecture as to the injurious effect on competition, stated that (p. 651)—

> * * * it is not necessary that the facts point to any particular trader or traders. It is enough that there be present or *potential* substantial competition, which is shown by proof, *or appears by necessary inference,* to have been injured, *or to be clearly threatened with injury,* to a substantial extent, by the use of the unfair methods complained of. [Italics supplied.]

See also *Federal Trade Commission* v. *Raladam Co.*, 316 U. S. 149, 151–152; *Electro Thermal Co.* v. *Federal Trade Commission,* 91 F. (2d) 477, 480 (C. C. A. 9), certiorari denied, 302 U. S. 748.[19]

We submit, therefore, that the finding of the Administrator that indiscriminate enrichment of farina would tend to mislead and confuse consumers was supported by substantial evidence, was a finding within his special administrative competence, and was, therefore, conclusive.

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[19] The same test of likelihood rather than actuality is used in the trade-mark and false advertising cases where consumer confusion is as here the very issue. *McLean* v. *Fleming*, 96 U. S. 245, 251; *United Drug Company* v. *Obear-Nester Glass Company*, 111 F. (2d) 997, 999–1000 (C. C. A. 8), certiorari denied, 311 U. S. 665; *Charles Broadway Rouss, Inc.* v. *Winchester Co.*, 300 Fed. 706, 723–724 (C. C. A. 2), certiorari denied, 266 U. S. 607.

B. Where there is a tendency toward consumer confusion, the Administrator may promulgate standards of identity which exclude variants even if wholesome and properly labeled

We have shown in the preceding point that the Administrator's finding that indiscriminate enrichment of farina would tend to confuse and mislead consumers is supported by substantial evidence and must, therefore, be accepted. But the court below held that, in any event, the Act does not authorize standards which exclude harmless ingredients disclosed by the manufacturer, and that even if it did the existence of a tendency to confuse and mislead is not a relevant consideration in the promulgation of standards of identity.

We submit that this conclusion is negated both by the text and the legislative history of the Act, and that standards of identity are not restricted by the tests of "honesty and fair dealing in the interest of consumers" to mere protection against false labeling.

1. *The text and history*[20] *of the Act.*—Section 401 of the Act authorizes the Administrator to fix and establish "a reasonable definition and standard of identity" when such action will in his judgment promote honesty and fair dealing in the interest of consumers. It is our position that these words

[20] We shall consider the question initially apart from an examination of the meaning of the words "honesty and fair dealing in the interest of consumers." In the second portion of this point (*infra*, pp. 45–52) we shall show that this clause,

authorize the Administrator to issue a definition and standard of identity which limits the composition of the defined food to ingredients specified in the definition, regardless of label disclosures and wholesomeness of proposed variants. The effect of the decision below, however, is to require every definition and standard to include a blanket clause permitting any nondeleterious variation which is disclosed by labeling.[21]

The terms of Section 401 are not consonant with this interpretation. To "define" is—

> To mark the limits of; to determine with precision or to exhibit clearly the boundaries of; as, to *define* the extent of a kingdom; to make distinct or fix in outline or character. *Webster's New International Dictionary.*

This is the sense in which courts have used the word in other contexts. *State* v. *Gardner*, 151 La.

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far from restricting the Administrator's authority, itself reinforces the conclusion that the Administrator may exclude wholesome ingredients in a standard of identity.

[21] Perhaps the decision goes even further than stated in the text. The court said: "the truth as to a food for which a standard has been fixed permits it to escape the indictment of being misbranded." (R. 685.) This seems to mean that even if the definition and standard need not contain a blanket variation clause, departures from the standard are permissible if disclosed by labeling. This is contrary to Section 403 (g) (21 U. S. C., Sec. 343 (g)) which provides that a food for which a standard has been adopted shall be deemed misbranded "unless it conforms to such definition and standard." Respondent has not maintained that standards were not exclusive under Section 403 (g), but only that the standards should be so phrased as to include his particular product.

874, 878, 92 So. 368, 370 (1922); *West Branch Novelty Co.* v. *Bloom*, 31 F. Supp. 673, 679 (E. D. Pa.). A "standard" is—

> That which is established by authority, custom, or general consent, as a model or example; criterion; test; in general, a definite level, degree, material, character, quality, or the like, viewed as that which is proper and adequate for a given purpose. *Webster's New International Dictionary*

That standards of identity are expected to put a definite limit upon the composition of foods is reinforced by the language of Section 401 dealing with optional ingredients:

> * * * In prescribing a definition and standard of identity for any food or class of food in which optional ingredients *are permitted*, the Administrator shall, for the purpose of promoting honesty and fair dealing in the interest of consumers, designate the optional ingredients which shall be named on the label. * * * [Italics supplied.]

Plainly, this contingent and permissive language contemplates cases in which optional ingredients will not be permitted at all; unless this is so, the clause is without meaning. This is borne out further by the form of Section 302 (g) of S. 5 (74th Cong., 1st Sess.), the predecessor of Section 403 (g) of the Act; it provided that a food should be deemed misbranded if

its label fails to bear * * * if so required by such regulations *when such definition and standard permits optional ingredients* * * * the common names of such optional ingredients as are present in such food. S. 5, 74th Cong., 1st Sess., Sec. 302 (g) (Dunn, 194)." [Italics supplied.]

This *power* to permit optional ingredients cannot be construed as an *obligation* to permit any disclosed non-deleterious addition, or, in other words, to exclude only deleterious or concealed ingredients, for to do so renders identity standards nugatory. Deleterious ingredients would in any event be barred by Section 402 which prohibits adulteration, and disclosure of ingredients of non-standardized foods is required by Section 403 (i). Indeed, if the narrow view of the function of identity standards were adopted, the only effect of promulgation of such standards, after elaborate hearings and review (*supra*, pp. 3–4), would be to relax disclosure requirements, since required ingredients of a standardized food and optional ingredients not specifically designated by the Administrator to be

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[11] The documents of the legislative history of the Act are collected in Dunn, *Federal Food, Drug, and Cosmetic Act* (1938), which appears to be complete except for hearings, from which only excerpts are given. Passages appearing in Dunn are herein cited "Dunn, —." On the relationship between the several bills leading to the present Act, Cavers, *The Food, Drug, and Cosmetic Act of 1938: its Legislative History and its Substantive Provisions*, 6 Law & Contemp. Prob. 2.

named on the label need not be disclosed. Sections 401 and 403 (g).

In addition, the contrasting treatment of labelling in connection with *identity* standards on the one hand and *quality* standards on the other confirms the conclusion that labeling was not intended to offer an escape from conforming to the definition of foods in standards of identity. As has been noted, Section 403 (g) requires a food purporting to be or represented as the food for which a definition and standard of *identity* has been prescribed to conform "to such definition and standard." In contrast, Section 403 (h) requires only that the food be labeled substandard if it fails to comply with *quality* standards fixed by the Administrator.[23] This distinction stems from a similar differentiation previously made by Congress between a standard of identity for butter[24] and the quality standards provided for certain canned foods by the McNary-Mapes Amendment to the Food and Drugs Act of 1906.[25] In the Butter Standard Act no

[23] In Section 501 (b) (21 U. S. C., Sec. 351 (b)), relating to drug standards, where departures from the standards are contemplated, provision is expressly made for such departures with appropriate label declarations.

[24] The Butter Standard Act of 1923, 42 Stat. 1500, 21 U. S. C. Section 321a. See discussion, *infra*, p. 42.

[25] Act of July 8, 1930, 46 Stat. 1019. The amendment added to the categories of misbranding in Section 8 of the 1906 Act the following:

[An article should be deemed to be misbranded . . . in the case of food:]

"Fifth. If it be canned food and falls below the standard of quality, condition, and/or fill of container, promulgated

provision is made for variations or for labeling of variations. In the McNary-Mapes Amendment, however, express provision is made for the sale of canned goods which are substandard in quality, conditioned upon an informative label statement. The distinction is emphasized in the committee reports on the bill which became the 1938 Food, Drug, and Cosmetic Act, listing the several effects of the new provisions:

> Definitions and standards of *identity* are provided under which the *integrity of food products* can be effectively maintained.
>
> *Informative labeling of foods as to quality and composition* is required for the information and guidance of consumers. Emphasis is placed on the informative labeling of special dietary food, such as that for infants and invalids. H. Rep. No. 2139, 75th Cong., 3rd Sess., p. 2 (Dunn, 816). See also H. Rep. No. 2755, 74th Cong., 2d Sess., p. 4 (Dunn, 553). [Italics supplied.]

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by the Secretary of Agriculture for such canned food and its package or label does not bear a plain and conspicuous statement prescribed by the Secretary of Agriculture indicating that such canned food falls below such standard. * * * The Secretary of Agriculture is authorized to determine, establish, and promulgate, from time to time, a reasonable standard of quality, condition, and/or fill of container for each class of canned food as will, in his judgment, promote honesty and fair dealing in the interest of the consumer; and he is authorized to alter or modify such standard from time to time as, in his judgment, honesty and fair dealing in the interest of the consumer may require. The Secretary of Agriculture is further authorized to prescribe and promulgate from time to time the form of statement which must

The maintenance of the integrity of a food product patently deals with the food itself, not its labeling.

The purpose of the enactment of Section 401, as revealed in its legislative history, also indicates that definitions and standards of identity were intended to be exclusionary. The principal reason urged in favor of identity standards was to dispense with the necessity of proving, in every case where adulteration or misbranding was charged, that the proper composition of the food involved was that which the government claimed.[26] For example,

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appear in a plain and conspicuous manner on each package or label of canned food which falls below the standard promulgated by him, and which will indicate that such canned food falls below such standard, and he is authorized to alter or modify such form of statement, from time to time, as in his judgment may be necessary. * * * Nothing in this paragraph shall be construed to authorize the manufacture, sale, shipment, or transportation of adulterated or misbranded foods."

[26] The Annual Report of the Food and Drug Administration for the fiscal year ending June 30, 1933, included the following statement with reference to the identity standard provisions of S. 1944, 73rd Cong., which had just been introduced:

"The present law gives the Department of Agriculture no authority to establish legal standards for food products, except in the limited field of canned foods. The food standards announced by the Department are wholly advisory in character and compliance is a voluntary matter on the part of the manufacturer. Such advisory standards are based upon the consensus of consumer understanding and upon good manufacturing practice. To prove that a product sold within the jurisdiction of the Food and Drugs Act and that fails to comply with the advisory standard is adulterated or misbranded, it is necessary for the Department to present to the court and jury convincing evidence that the advisory

Section 402 (a) (1) of the Act provides that a food shall be deemed adulterated if it contains "any poisonous or deleterious substance which may render it injurious to health," with a qualification in case the substance "is not an added substance." Section 402 (a) (2) deals with "added poisonous or added deleterious" substances. Section 402 (b) covers adulteration by abstraction of valuable constituents or substitution of substances or additions which make the food appear better or of greater value than it is. As was stated in Senate Committee reports:

> These provisions in themselves imply the existence of definitions and standards of identity, since no one can tell when an article is adulterated under them without first determining definitely what constitutes

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standard does represent the actual composition of the product expected by the consumer and recognized by the majority of the trade. Proof that the food on trial does not meet the advisory standard is of no avail unless the validity of the standard is first established. This imposes a double burden of proof upon the Government as well as the expense of bringing into court trade and consumer witnesses who are prepared to testify that the advisory standard accurately represents the material in question. It has long been recognized that this necessity imposes a handicap of undue proportions upon the Government and that the lack of legal standards is a distinct disadvantage to ethical manufacturers who are forced to compete with products which differ from the advisory standards. The establishment of food standards having the force and effect of law will vastly simplify the problem of enforcement and will unquestionably be of great advantage to the consuming public and to the manufacturer of legal products."

the unadulterated product. S. Rep. No. 493, 73rd Cong., 2d Sess., p. 10 (Dunn, p. 119); S. Rep. No. 361, 74th Cong., 1st Sess., p. 10 (Dunn, p. 245).

But if standards do not exclude ingredients it would still remain necessary in every case to prove that the product in question differs from some norm established by the customs of housewives or trade practice, since the "standard" itself would necessarily be so inclusive that it would not fix a norm but would permit the addition of an unlimited number of "added substances." In each case a showing would be required not only that the disputed ingredient is injurious to health or makes the product appear better or of a greater value than it is, but also that it is an "added substance", i. e., not one properly or usually included in a food of this category.

The difficulties intended to be eliminated by the identity standards provisions of Section 401 are illustrated by *United States* v. *Ten Cases, More or Less, Bred Spred*, 49 F. (2d) 87 (C. C. A. 8) [27] in

[27] Two other Bred Spred cases also figure in the legislative history. They are *United States* v. *Fifteen Cases of Bred Spred*, 35 F. (2d) 183 (C. C. A. 7), in which the Government was held estopped by the judgment in *United States* v. *49½ Cases of Bred Spred* (E. D. Mich.), reported in U. S. Dept. of Agriculture, *Decisions under The Pure Food and Drugs Act* (1934), p. 1201. This last case construed the distinctive-name proviso of Section 8 of the Act, 34 Stat. 768–771, 21 U. S. C. (1934 ed) sec. 10, as exempting any food sold under a distinctive name from compliance with all the misbranding and adulteration provisions of the old Act unless it actually

which the Government libelled under the 1906 Act a product sold under the name "Bred Spred." This product resembled jam but contained only half the normal fruit content, as measured by trade and household practice. It sold for a price only slightly less than jam. The Court held that the product was neither adulterated nor misbranded:

> * * * The mere fact that the product contained fewer strawberries than some other product, e. g., jam, does not show that Bred Spred was inferior to jam; nor does it show that a comparison with jam was called for by the statute unless Bred Spred was being palmed off on the public as jam. No showing of this kind was made.

The House Committee on Interstate and Foreign Commerce referred to this decision as justifying the necessity of standards of identity. The patent intent to render the *Bred Spred* decision obsolete through the effect of the identity standard provisions makes it clear that the Act gives the Adminis-

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contained additions of poisonous or deleterious ingredients. The Chief of the Food and Drug Administration referred several times to the latter *Bred Spred* cases in his testimony in support of the deletion of the old distinctive-name clause from the new bills, Hearings, Subcommittee of S. Committee on Commerce, S. 1944, 73rd Cong., 2d Sess., p. 14 (Dunn, 1052); Hearings, S. Committee on Commerce, S. 2800, 73rd Cong., 2d Sess., p. 512 (Dunn, 1123); Hearings, Subcommittee of H. Committee on Interstate and Foreign Commerce, H. R. 6906, H. R. 8863, H. R. 8941, and S. 5, 74th Cong., 1st Sess., pp. 45–55 (Dunn, 1237–1246). Only at the last-cited passages are the identity-standard point and the distinctive-name point both under direct discussion.

trator greater authority than the court below attributed to him. For if the standard of identity authorized by Section 401 were limited in its scope as required by the court below, such products as Bred Spred would be immune since, though not comporting with normal standards, they nevertheless are honestly labeled and nondeleterious. This is precisely the result intended by Congress to be avoided.[28]

The history of standard making lends further support to the view that standards were intended to be exclusionary. The Food and Drug Administration began issuing food standards in 1903 under a congressional appropriation authorizing the Secretary of Agriculture—

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[28] H. Rep. No. 2139, 75th Cong., 3rd Sess., p. 5 (Dunn, 819).

"Section 401 provides much needed authority for the establishment of definitions and standards of identity and reasonable standards of quality and fill of container for food. One great weakness in the present food and drugs law is the absence of authoritative definitions and standards of identity except in the case of butter and some canned foods. The Government repeatedly has had difficulty in holding such articles as commercial jams and preserves and many other foods to the time-honored standards employed by housewives and reputable manufacturers. The housewife makes preserves by using equal parts of fruit and sugar. The fruit is the expensive ingredient, and there has been a tendency on the part of some manufacturers to use less and less fruit and more and more sugar.

"The Government has recently lost several cases where such stretching in fruit was involved because the courts held that the well-established standard of the home, followed also by the great bulk of manufacturers, is not legally binding under existing law. * * *"

> to establish standards of purity for food products and to determine what are regarded as adulterations therein, for the guidance of the officials of the various States and of the courts of justice * * *. Act of June 3, 1902, 32 Stat. 286, 296.

The first such standards were prefaced by a statement of "Principles on which the Definitions and Standards are Based." The list of principles included:

> 3. The definitions are so framed as to exclude from the articles defined substances not included in the definitions.[29]

The advisory standards were, however, not generally regarded by the federal courts as binding upon them[30] and it therefore became a principal pur-

[29] U. S. Department of Agriculture, Circular No. 10, Standards of Purity for Food Products (1903) p. 3. A similar statement appears in the successive revisions of the standards pamphlet. Circular No. 13 (1904) p. 3; Circular No. 19 (1906) p. 4; U. S. Department of Agriculture, Service and Regulatory Announcements, Definitions and Standards for Food Products (1927), revised and reissued 1928, 1931, 1932, 1933, 1936) p. 1. Farina first appears in the 1928 revision, p. 8: "Farina is the purified middlings of hard wheat other than durum".

[30] *United States* v. *One Hundred Barrels of Vinegar*, 188 Fed. 471 (D. Minn.); *United States* v. *W. B. Wood Mfg. Co.*, (E. D. Mo.), reported in *Decisions of Courts in Cases under the Federal Food and Drugs Act* (1954) 1002, 1003, affirmed on other grounds, 292 Fed. 133 (C. C. A. 8); but cf. *United States* v. *Frank*, 189 Fed. 195 (S. D. Ohio). The advisory standards were, however, adopted as legal standards by a number of State legislatures, e. g., California, G. L. 1923, Act 57, sec. 3, sustained in *Cleveland Macaroni Co.* v. *State Board of Health*, 256 Fed. 376 (N. D. Calif.).

pose of legislation in this field subsequent to the 1906 Food and Drug Act to give legal sanction to the standards promulgated by the Food and Drug Administration. It is significant that none of these advisory standards included a blanket clause permitting the addition of ingredients simply because they were nondeleterious and disclosed by labeling.

Nor did Congress include such a blanket clause for optional ingredients when it enacted a definition and standard of identity for butter in 1923. The Butter Standard Act was entitled "An Act To define butter and provide a standard therefor," and provided:

> for the purposes of the Food and Drug Act of June 30, 1906 (34 Stat. 768), "butter" shall be understood to mean the food product usually known as butter, and which is made exclusively from milk or cream, or both, with or without common salt, and with or without additional coloring matter, and containing not less than 80 per centum by weight of milk fat, all tolerances having been allowed for. (42 Stat. 1500 (21 U. S. C., Sec. 321a).)

In commenting on the bill the Chairman of the House Committee said:

> The only things you can put into [butter] are salt, casein, the butter fat, and water. That is what the definition provides.[31]

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[31] Hearings, H. Committee on Agriculture on H. R. 12053, 67th Cong., 2d Sess., p. 24; see also H. Rep. No. 1141, 67th Cong., 2d Sess., p. 4.

Clearly, other healthful ingredients are excluded from the standard for butter. In describing the operation of the Butter Act to the congressional committees which were considering the identity-standard provisions of the 1938 Food, Drug, and Cosmetic Act, the Chief of the Food and Drug Administration pointed out the enforcement advantages of exclusionary standards, and characterized them as standards of production and manufacturing practice, not labeling standards.[32] Thus plainly the butter standard legislation, exemplar of the standards of identity provided for by Section 401, makes no provision for variations contingent upon labeling.

A final indication of understanding that standards of identity might condemn wholesome non-

[32] "Prior to the passage of the measure amending the Food and Drugs Act by requiring that butter contain not less than 80 percent fat, the condition was chaotic. Butter was produced and sold which varied from 75 to 85 percent fat. In the absence of power to standardize its production, the public was victimized not only, but the unbridled competitive situation was rapidly bringing about a condition of trade demoralization. Since the establishment of the legislative standard, enforcement operations have been simplified, manufacturing practices have been standardized, and, most important of all, the public has been effectively protected." Hearings, Subcommittee of S. Committee on Commerce, 74th Cong., 1st Sess., S. 5, p. 359 (Dunn, 1231). See also Hearings, Subcommittee of S. Committee on Commerce, 73d Cong., 2d Sess., S. 1944, p. 21 (Dunn, 1059), and Hearings, Subcommittee of H. Committee on Interstate and Foreign Commerce, 74th Cong., 1st Sess., H. R. 6906, H. R. 8805, H. R. 8941, S. 5, p. 51 (Dunn, 1242).

conforming foods, without benefit of reprieve by label disclosure, appears from the legislative history of the provisions relating to standardization of fruits, vegetables, and cheese. The almost complete exemption of fruits and vegetables[23] from the Administrator's power to standardize had its genesis in the fear of apple and pear growers that identity standards for these fruits could, in the absence of specific exemption, be so set in terms of sugar, acid, and solid-content that entirely wholesome products of certain regions could not fall within the standards and would thus be excluded from the national market. 79 Cong. Rec. 4861–4862, 4905–4906 (Dunn, 324–326). It was assumed by proponents of the exemption and presumably by Congress which granted the exemption that a standard of identity for apples might be such as to exclude sound, nondeleterious apples not mislabeled in any way. Conversely, when it was proposed to eliminate cheese from the standard making power, a representative who opposed the cheese exemption expressly recognized that given definitions and standards of identity "we could not have certain

[23] "SEC. 401 * * * *Provided*, That no definition and standard of identity and no standard of quality shall be established for fresh or dried fruits, fresh or dried vegetables, or butter, except that definitions and standards of identity may be established for avocadoes, cantaloupes, citrus fruits, and melons. * * * Any definition and standard of identity prescribed by the Administrator for avocadoes, cantaloupes, citrus fruits, or melons shall relate only to maturity and to the effects of freezing."

types of cheese." 83 Cong. Rec. 7795 (Dunn, 865); yet the power to standardize cheese was restored. 83 Cong. Rec. 7795, 7902 (Dunn, 905, 961).

2. *The effect of the clause "honesty and fair dealing in the interest of consumers."*—We submit therefore that the terms and history of Section 401 establish that the Administrator was entrusted with authority to issue standards of identity which were not required to include every wholesome variant included by any manufacturer in the field. This conclusion would seem to be necessary if the regulation is to be a "standard of identity" within the ordinary import of those words. And similarly, the conclusion would seem to be inherent in the clause "honesty and fair dealing in the interest of consumers" if those words are to be given substantial meaning. The promulgation of a standard of identity to promote honesty and fair dealing in the interest of consumers is, we submit, particularly appropriate in a field where, as here, there are multiple variations in any class of important food to an extent that the consumer is confused and misled. For where there is consumer confusion, a standard of identity to minimize such confusion would seem plainly to be action to promote honesty and fair dealing in his behalf. And the goal of minimizing confusion and promoting honesty and fair dealing would scarcely be advanced by a "standard of identity," if such it could be called, which was required to be drawn so comprehensively that every wholesome variant were permitted to be included.

The court below, however, found in the phrase "honesty and fair dealing in the interest of consumers" not confirmation of this conclusion, but a restriction upon the Administrator's authority. Confusion of consumers, in the court's view, was as a matter of law irrelevant to the promotion of honesty and fair dealing. Whatever effect this interpretation gives to the word "honesty," it accords no substance to "fair dealing." And it is contrary to well established judicial interpretation of the statutory phrase.

The scope of the concept "honesty and fair dealing" has received judicial consideration primarily in cases involving protection of businessmen and the public against unfair competitive practices. In this field it is well settled that injunctive relief may be had on proof that defendant's conduct tends to deceive the public; it is unnecessary to show actual deception[14] or fraudulent intent.[15] "Confusion" of the public resulting from "deliberate or unintentional simulation" is regarded as equivalent to deception.[16] And misleading first impressions de-

[14] *McLean* v. *Fleming*, 96 U. S. 245, 251; *Rosenberg Bros. & Co.* v. *Elliott*, 7 F. (2d) 962, 966–967 (C. C. A. 3); *Charles Broadway Rouss, Inc.* v. *Winchester Co.*, 300 Fed. 706, 724 (C. C. A. 2), certiorari denied, 266 U. S. 607. For the phrase "honesty and fair dealing," see the *Rosenberg* case, and discussion in Nims, *The Law of Unfair Competition and Trade Marks* (3d ed., 1929), pp. 26–27.

[15] *Straus* v. *Notaseme Hosiery Co.*, 240 U. S. 179, 182; *Coty, Inc.* v. *Parfums de Grande Luxe*, 298 Fed. 865, 869–871 (C. C. A. 2).

[16] *Henry Maish Co.* v. *Farm Craft Foods*, 37 F. Supp. 1013, 1015 (E. D. N. Y.); see also *United Drug Company* v. *Obear-Nester Glass Company*, 111 F. (2d) 997, 1000 (C. C. A. 8), certiorari denied, 311 U. S. 665; *Florence Manufacturing Co.* v. *Dowd & Co.*, 178 Fed. 73, 75–76 (C. C. A. 2).

rived from labeling will justify judicial relief, however accurate the literal statement."

Any doubt concerning the applicability of these principles to food standardization for the promotion of "honesty and fair dealing" is settled by the decision of this court in *Houston* v. *St. Louis Independent Packing Co.*, 249 U. S. 479, in which this Court refused to disturb a determination of the Secretary of Agriculture under the Meat Inspection Act,[11] that it would be deceptive to label as "sausage" an article containing more than 2 per cent cereal, even with qualifying words showing the presence of cereal in excess of 2 percent. The Meat Inspection Act provided that "no such meat or meat food products shall be sold or offered for sale * * * under any false or deceptive name" and authorized the Secretary to make rules and regulations necessary for the efficient enforcement of the Act. (21 U. S. C., Secs. 75, 89). The Court stated (249 U. S. at p. 487):

> * * * we cannot say that it was an abuse of discretion to prohibit the use of the word "sausage" as applied to it, rather than to prescribe qualifying terms explanatory of

[11] *See United States* v. *Ten Barrels of Vinegar*, 186 Fed. 309 (E. D. Wis.); *Heusner & Son* v. *Federal Trade Commission*, 106 F. (2d) 596 (C. C. A. 3). In the *Heusner* case the court refused to modify an order that petitioner cease and desist from using the word Havana on cigars not made in Cuba, by permitting such use with the qualifying words "Notice. These Cigars are made in the United States and only of United States tobacco."

[11] 21 U. S. C., Sec. 71.

it. Few purchasers read long labels, many cannot read them at all, and the act of Congress having committed to the head of the department, constantly dealing with such matters, the discretion to determine as to whether the use of the word "sausage" in a label would be false and deceptive or not, under such circumstances as we have here, this court will not review, and the Circuit Court of Appeals should not have reviewed and reversed the decision of the Secretary of Agriculture.

See also *United States* v. *95 Barrels Cider Vinegar*, 265 U. S. 438, 442–443.

It will be noted that the *Houston* case, like the instant case, turned not on any question of unwholesomeness, but upon the question whether a requirement of label disclosure is the outermost reach of an administrative power to prevent deception resulting from variations in the product.*

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* The Circuit Court of Appeals for the Eighth Circuit, whose construction of the statute was reversed by the Supreme Court, had fallen into precisely the error of the court below in the instant case, as is apparent from the language, below at an earlier stage of the case, *St. Louis Independent Packing Co.* v. *Houston*, 215 Fed. 553, 560, 561, (treated as the law of the case in the judgment which the Supreme Court reversed, *St. Louis Independent Packing Co.* v. *Houston*, 242 Fed. 337):

"* * * The subdivision in question prohibits a sale under any false and deceptive name and such it probably would be to sell a combination of sausage and cereal under the name of sausage, but not under the name of sausage and cereal. * * * The question is simply: Could he prohibit the making of a compound which was sound, healthful, wholesome, and free

The use of variant partial enrichments which the public is unable to identify by label so as to make an intelligent choice, and in its ignorance assumes to be "a short-cut to a balanced diet" (R. 177), constitutes a disappointment of public expectation as effective as the dilution by addition of substantial quantities of cereal to a sausage which the public in its ignorance assumes to be completely sausage.

The term "honesty and fair dealing in the interest of consumers" is at least as inclusive as the words "false and deceptive" which were the test of the Secretary's action under the Meat Inspection Act.

If, as we have shown, confusion facilitates deception of the public and is therefore inconsistent with honesty and fair dealing, and if labelling may be an insufficient protection against confusion, it is plain that standardization, i. e., exclusion of some of the variables which would confuse and be confused by the public, is an effective method of promoting honesty and fair dealing. This Court expressly sanctioned such a rationale for standardization in *Pacific States Box Co.* v. *White*, 296 U. S. 176, 181–182, in which state regulations

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from dyes, chemicals, preservatives, or ingredients which render such unfit for human food by a mere regulation? We are constrained to say that he cannot. 'A compound of beef and pork would not entitle the Secretary of Agriculture to prohibt the words "beef" and "pork" to appear in the title and to condemn all such compounds on the label of which they appear."

fixing the form and dimensions of containers were upheld. This Court in effect took judicial notice of the deceptive effect of unrestricted variations. Speaking for the Court, Mr. Justice Brandeis pointed out that the power to prescribe standard containers "to protect buyers from deception" was unchallenged, and that "obviously, a multitude of shapes and sizes of packages tends to confuse the buyer" (p. 181). Accordingly the Court refused to interfere with the exercise of administrative discretion in the selection of the precise forms and dimensions prescribed for containers. Compare also dissenting opinion of Justices Holmes and Brandeis in *Burns Baking Co.* v. *Bryan*, 264 U. S. 504, 517–534.[*]

It is clear that if confusion is minimized and honesty and fair dealing are promoted in enriched foods, public health will benefit. The court below seized upon this consequence of standardized enrichment as a basis for holding that the Administrator was irresponsibly furthering consumer health and public education in respect of dietary requirements instead of furthering honesty and fair-

[*] The Administrator's power to designate a minimum selection of vitamin and mineral additions does not differ in principle from his power to fix quantitative minima to prevent infinitesimal additions on which exaggerated advertising claims might be based. His authority to fix such quantitative minima and the desirability of doing so have not been questioned at any stage of these proceedings. See R. 45, 116, 136–167, 221, 409, 463, and 470.

dealing (R. 684–686).[41] But we submit that the improvement in public health resulting from the regulations under review is a practical advantage of the standards which is not fatal to their validity. The standards are genuinely designed to promote honesty and fair dealing through the elimination of confusion and misleading merchandising of vitamin and mineral enriched foods. The regulations do not require anyone to produce or buy "enriched farina"; the consumer can and must still choose for himself. The Administrator has merely taken steps to prevent deception likely to arise from representations of dietary efficacy implicit in the addition of special nutrients in farina and explicit in the merchandising of these products. In doing so he has considered the state of consumer education as an element in determining the probability of deception and in weighing the adequacy of the suggested alternative ways of combatting deception.

[41] It may be noted that, in any event, promotion of public health is not foreign to the purposes of the Food, Drug, and Cosmetic Act. Much of the hearings, debates, and committee reports were concerned with the effect of the legislation on health. The bill was captioned, "To prevent the adulteration, misbranding, and false advertisement of food * * * for the purposes of safeguarding the public health, preventing deceit upon the purchasing public, and for other purposes" (S. 5, 75th Cong., 1st Sess., Dunn, 636). It retained that title until a last minute abbreviation to the present form: "An Act to prohibit the movement in interstate commerce of adulterated and misbranded food, drugs, devices, and cosmetics, and for other purposes." 83 Cong. Rec. 7889, 7903; H. Rep. No. 2716, 75th Cong., 3d Sess., p. 21 (Dunn, 963, 991).

The situation with respect to vitamin D, respondent's enrichment, illustrates the relationship between public health, public education, and the misleading and confusing of the public. As a matter of public health it may be debatable whether vitamin D deficiency causes more harmful results than deficiency of the elements of whole wheat required by the standard. But consumer expectations have been conditioned to regard milled wheat products as nutritionally deficient in particular comparison to whole wheat (R. 45, 116, 122, 125, 150, 310–311, 500), not to sunshine or fish liver oil, the sole sources of vitamin D. To permit indiscriminate enrichment of a wheat product by leaving out the nutrients lost in milling whole wheat, while inserting those derived from sunshine or fish liver, or any other unrelated source of vitamins, at the miller's whim, would confuse and mislead by failing to take account of the one reasonably clear idea about nutrition which the record shows is safely in the public mind, that milled wheat products are somehow inferior to whole wheat.

C. The Administrator's treatment of vitamin D is reasonable

We have shown in Point A that the Administrator's finding that indiscriminate enrichment would tend to confuse and mislead consumers is supported by substantial evidence. He was, therefore, entitled to promulgate standards which would mini-

mize such confusion and misleading, and, as we have urged in Point B, the Administrator was authorized, under the Act, to draw these standards in such a manner as to exclude ingredients even if they are nondeleterious. There remains only the question whether there was a reasonable basis for the particular method selected by the Administrator, *viz*, exclusion of vitamin D from the definition of farina and a requirement that enriched farina, in which vitamin D is permitted, must contain four other named nutrients. We submit that there was such a basis and that the standards are therefore conclusive upon review.

1. At the outset the precise scope of the inquiry in this branch of the case must be delimited. If standards of identity issued under Section 401 of the Act may exclude nondeleterious ingredients, as we submit they may, and as indeed they must if confusion arising from multiple variations is to be minimized, plainly the Administrator must have a wide discretion in determining what to include and what to exclude. His problem is one of administrative regulation or legislation; and as in the ordinary process of legislation, there arises the familiar problem of where to draw the line. Accordingly, in testing the reasonableness of the line which is drawn, the issue cannot be whether the line may have been drawn at some other point. Indeed, it may be conceded *arguendo* that the Administrator

could reasonably have drawn the farina standard so as to permit the inclusion of vitamin D as an optional ingredient.[42] But clearly in this type of action it can rarely be established that any particular standard is impelled as the only correct one. The process of arriving at a proper regulation, like the congressional process of arriving at a law, is not a matter of simple mathematical or logical deduction leading to a single answer. Reasonable men basing their action on the same facts and findings could arrive at entirely different regulations, none of which could be properly characterized as arbitrary, whimsical, or unreasonable. The test of the validity of regulations of this nature, if judicial judgment is not entirely to replace administrative *expertise*, must therefore be limited to the inquiry whether the particular alternative which the administrative agency selected, among many alternatives, to achieve the objectives of the act under which it operates is one which a rational person could have chosen. *Final Report of Attorney Gen-*

[42] But see the testimony against permitting the inclusion of vitamin D in farina. R. 101-102, 361, 386, 413, 497. And in any event, presumably, if vitamin D were entitled to be included as an optional ingredient, a multitude of other nondeleterious ingredients has equal claim to optional inclusion. If the inclusion of vitamin D would logically require permission to include all other nondeleterious ingredients, there would be no advance to the goal of elimination of confusing and misleading consumers and no "standard" at all in our view of the meaning of that word.

eral's Committee on Administrative Procedure, Sen. Doc. No. 8, 77th Cong., 1st Sess., p. 117.

This test, we submit, plainly is met in the instant case. As we have seen, some elimination was permissible and necessary to promote honesty and fair dealing by minimizing consumer confusion. The nature and history of the enrichment problem in relation to farinas, which we have summarized above (*supra,* pp. 18–21), furnish a sound basis for the particular choice made by the Administrator. Thus, the evidence, as we have shown, establishes that the original whole wheat berry, the ultimate source of farina products, includes the four ingredients, B_1, riboflavin, nicotinic acid, and iron, which the Administrator required as ingredients of enriched farina. Each of these ingredients is important to the diet; widespread deficiencies in these ingredients exist; and yet, by virtue of an evolution in milling processes, these vitamin and mineral constituents, particularly in respect of farina, were largely abstracted.

It is clear, therefore, that the Administrator's standards of farina and enriched farina were not artificial but rather an accommodation to existing natural, historical, and dietary phenomena. In essence, the farina standard is simply the definition of the basic product remaining after the milling process, while, on the other hand, the required elements of enriched farina result roughly in a restoration of the ingredients originally in the whole

wheat berry. In contrast, vitamin D, which respondent insists should have been permitted as an optional ingredient in the standard of farina, is not naturally related to farina; that vitamin is not contained in appreciable quantities in wheat, and its addition to farina is in that respect artificial." Moreover, to permit the addition of single vitamins to farina would blur the essential distinction in the identities of farina and enriched farina. We submit that, in these circumstances, there was a sound historical, natural, and dietary basis for the Administrator's treatment of vitamin D."

"Vitamin D and calcium, the optional ingredients of enriched farina, were permitted on the ground that they can readily be added to wheat and their deficiency is a serious shortcoming in the dietary of infants (Finding 40, R. 618; R. 422–424, 555–556).

"The conclusion is further fortified by the testimony of expert witnesses: To achieve a product which would meet consumer expectations by making a significant amelioration of the nutritional shortcomings of milled wheat, some industry witnesses proposed only vitamin B_1 as required, with other vitamins, calcium and iron as additional optional ingredients (R. 251, 443). This proposal was rested on the facts, already noted, that B_1 is milled out of wheat to a greater extent than any other factor on which figures were available and that B_1 deficiency is probably the most widespread in the country (see supra, pp. 18, 21). But other testimony was to the effect that diets lacking in B_1 are particularly likely to be deficient also in other members of the B complex, such as nicotinic acid and riboflavin (R. 287, 366, 388; cf. 443). These considerations of multiple deficiency led to recommendations of enrichment on a "restoration" basis, i. e., reintroducing into wheat products those nutritive elements which had been lost in the milling process (R. 42.

Nor are the standards unreasonable because, as the respondent has urged, the addition of the required ingredients are so expensive as to destroy his business. If the regulation is otherwise reasonable and within the statutory authority, it is immaterial that a particular manufacturer must change his methods or product or even that some products may be driven from the market. Cf. *Mugler* v. *Kansas*, 123 U. S. 623, 628–633; *Powell* v. *Pennsylvania*, 127 U. S. 678, 683–684; *Hebe Company* v. *Shaw*, 248 U. S. 297, 302–303; *United States* v. *Carolene Products Co.*, 304 U. S. 144, 151. But in any event, the evidence establishes that the enrichment required is neither impracticable nor expensive. Vitamin B_1, riboflavin, nicotinic acid, and iron can be practicably replaced in farina by changes in the milling process designed to retain its natural content, or by the use of recently developed vitamin concentrates derived from natural sources or synthesized (R. 107, 128–131, 153–154). Although the cost of vitamins may appear to be high in terms of dollars per pound (e. g. B_1 costs $700

402). Still another witness favored "fortification" (R. 42, 104), i. e., not only reintroducing into the products the elements necessary to restore it to the approximate value of whole wheat, but also the addition of more of those elements than originally contained or the addition of other factors not originally contained, for the purpose of enabling the food to make good the deficiencies caused by other foods in the American dietary rather than making good only its own shortcomings. No witnesses who testified to the dangers of confusion from indiscriminate optional enrichment recommended less than "restoration."

per pound (R. 45, 65)), the minute quantities required results in an insignificant addition to the cost of production. The cost of the ingredients for enriching a barrel of flour was estimated at 35 to 75 cents (R. 365, 377, 477–479.) One witness testified that added vitamin B_1 would cost less than one tenth of a cent a pound and that the required enrichment would not substantially increase the price to consumers (R. 490, cf. R. 419). And the practice (R. 130–131, 268–269) among manufacturers of enriching their product by combinations of the ingredients here involved establishes that the Administrator's standard does not impose unfeasible or impracticable requirements.

2. Since, therefore, there was a reasonable basis for the exclusion of vitamin D in the standard of farina and its inclusion in combination in the standard of enriched farina, the Administrator's action is entitled to finality upon judicial review. The selection of means for effectuating the objectives defined in the Act is within the special province of the administrative agency; it is for the agency and not the reviewing court to say whether accurate labeling of a food constitutes sufficient protection against deception of consumers. *Houston* v. *St. Louis Independent Packing Co.*, 249 U. S. 479, 484. The doctrine that the conclusions of administrative tribunals are not to be "disturbed except in the plainest cast" applies "with especial force" where the judgments are involved in promulgating regulations and are necessarily prospec-

tive. L. Hand, C. J., *National Broadcasting Co., Inc.* v. *United States*, not yet reported (S. D. N. Y., November 16, 1942), Nos. 554–555, probable jurisdiction noted, December 14, 1942. We submit that in holding the regulations unreasonable, the court below substituted its own judgment for that of the Administrator's "in a domain of knowledge still shifting and growing, and in a field where judgment is therefore necessarily beset by the necessity of inferences bordering on conjecture even for those learned in the art." *Railroad Commission of Texas* v. *Rowan and Nichols Oil Co.*, 310 U. S. 573, 581.

CONCLUSION

For these reasons it is respectfully submitted that the judgment of the court below should be reversed.

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IN THE

SUPREME COURT OF THE UNITED STATES

OCTOBER TERM, 1942.

No. 424

FEDERAL SECURITY ADMINISTRATOR,
Petitioner,

vs.

THE QUAKER OATS COMPANY,
Respondent.

BRIEF FOR RESPONDENT IN OPPOSITION TO THE PETITION FOR WRIT OF CERTIORARI.

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PRELIMINARY STATEMENT.

The petitioner* asks this Court to review the decision of the Circuit Court of Appeals for the Seventh Circuit. The opinion of the Circuit Court of Appeals (R. 679-689) is reported in 129 Fed. (2nd) 76.

The essential facts may be stated in a short paragraph. For over ten years respondent, The Quaker Oats Company, has been marketing an admittedly highly nutritious product known as "QUAKER FARINA Wheat Cereal Enriched With VITAMIN D" (R. 218). The Administrator has specifically found or admitted that Vitamin D is very beneficial, particularly to infants and children who are large consumers of respondent's product, that respondent's prod-

*Respondent will in this brief follow the procedure adopted by petitioner in his petition and refer to him as "Administrator." Italics throughout this brief are supplied unless otherwise noted.

uct is truthfully labelled and that Vitamin D does not adulterate or dilute the product (R. 617, 626, 683). The Administrator promulgated two food standards; one for farina in which Vitamin D is not permitted to be added, the other for a theretofore unknown product which the Administrator called "Enriched Farina" in which he permitted the addition of Vitamin D but only upon condition that Vitamin B_1, riboflavin, nicotinic acid and iron be first added (R. 627, 637-8). As the Court below found from the record, there is no relationship between Vitamin D and the four above-named substances (R. 687).

The Administrator has urged in his petition four reasons for the granting of the writ of certiorari. It is respondent's view that none of these reasons is sufficient to justify this Court in granting the writ. Why these reasons are insufficient and why the decision of the Court of Appeals was clearly correct will be hereinafter pointed out in the Argument. For convenience, the reasons urged by the Administrator will be discussed in the order they are presented in his petition.

Under the heading "Questions Presented" the Administrator has in his petition omitted what we consider the most fundamental and important question presented in this case (Pet. 2). That question is whether or not Section 401 of the Federal Food, Drug and Cosmetic Act empowers the Administrator to bar from the market a wholesome and nutritious food which is truthfully and correctly labelled, and which is neither adulterated nor diluted.

SUMMARY OF THE ARGUMENT.

We have conformed our argument to that of the Administrator and take up his points urging that this Court review the decision of the Court below as follows:

1. The Administrator's first point is that this is the first case before this Court under the Federal Food, Drug and Cosmetic Act of 1938 and that "the conclusions of the Court below jeopardize *the food standards program*".

2. The Administrator contends that his finding that indiscriminate enrichment would tend to confuse and mislead consumers is clearly supported by substantial evidence, the alleged evidence being opinions dealing *"with probable future effects of present trends"* (Pet. p. 15).

3. The Administrator contends that "the *ill-advised skeptic* will pay as much for plain farina as for the superior product, enriched farina (cf R. 413); the *credulous* can be persuaded to pay as much for one vitamin as for four (cf R. 177)" and that action to protect the *ill-advised skeptic* and *the credulous* will promote honesty and fair dealing in the interest of *all* consumers (Pet. 16).

4. The Administrator contends that there was evidence in the record upon which to base the exclusion of Vitamin D as an optional ingredient in farina.

ARGUMENT.

1. In contending that the conclusions of the Circuit Court of Appeals for the Seventh Circuit "jeopardize *the food standards program*" (Pet. 12), the Administrator attempts for the first time to create an issue which cannot lawfully exist. We are concerned with a statute, a simple and plainly worded statute which the Administrator would ignore for his *food standards program*, or, as he sometimes says *"the enrichment program"* (Pet. 15).

Section 401 of the Federal Food, Drug and Cosmetic Act of 1938 (21 U. S. C. A. 341) prescribes and limits the power of the Administrator to establish definitions and standards of identity for foods. It reads:

> "Whenever in the judgment of the Administrator *such action will promote honesty and fair dealing in the interest of consumers*, he shall promulgate regulations fixing and establishing for any food, under its common or usual name so far as practicable, a *reasonable definition and standard of identity*, a reasonable standard of quality, and/or reasonable standards of fill of container: Provided, That no definition and standard of identity and no standard of quality shall be established for fresh or dried fruits, fresh or dried vegetables, or butter, except that definitions and standards of identity may be established for avocadoes, cantaloupes, citrus fruits, and melons. In prescribing any standard of fill of container, the Administrator shall give due consideration to the natural shrinkage in storage and in transit of fresh natural food and to need for the necessary packing and protective material. In the prescribing of any standard of quality for any canned fruit or canned vegetable, consideration shall be given and due allowance made for the differing characteristics of the several varieties of such fruit or vegetable. In prescribing a definition and standard of

identity for any food or class of *food in which optional ingredients are permitted*, the Administrator shall, for the purpose of promoting honesty and fair dealing in the interest of consumers, *designate the optional ingredients which shall be named on the label.* Any definition and standard of identity prescribed by the Administrator for avocadoes, cantaloupes, citrus fruits or melons shall relate only to maturity and to the effects of freezing".

The Administrator urges in effect (Pet. 12-13) that he has authority under the statute to bar the sale of a food (and thus make such sale a criminal offense), notwithstanding that (1) it is improved nutritionally; (2) it is wholesome and contains no harmful or deleterious ingredients; (3) it is not adulterated; (4) it is not diluted; and (5) it is correctly and truthfully labelled.

But Section 401 of the Federal Food, Drug and Cosmetic Act was never designed to destroy honestly conducted business in healthful foods which are truthfully and correctly labelled and neither adulterated nor diluted, and by destroying such business deprive the public of products which they need and want. Certainly such a construction for which the Administrator now contends is in no way in conformity with the purposes of the statute, which in the language of this Court, as applied to the earlier Food and Drug Act of 1906, are "to secure the purity of foods" and "to inform purchasers of what they are buying" (*U. S.* v. *Antikamnia Chemical Co.*, 231 U. S. 654, 665).

No important new question of Federal law is presented in this case. Section 401 of the Act, which petitioner characterizes as "the *important food standardization provisions*" of the statute, is patterned closely after a similar provision in the earlier Food and Drug Act of 1906 (21 U. S. C. A., Section 10 as amended July 8, 1930). In the amendment of July 8th, 1930, to Section 10 of the earlier

act, a provision empowering the Secretary of Agriculture to promulgate certain standards for canned foods was added to the statute. That section used language *identical* in its pertinent parts to the language in Section 401. It empowered the Secretary of Agriculture to promulgate *reasonable* standards of quality, etc., for the canned foods there covered, and he was limited in his power to promulgate such standards to such as would in his judgment "*promote honesty and fair dealing in the interest of the consumer.*" So since 1930 and until it was replaced by the 1938 Food, Drug and Cosmetic Act, the old 1906 Food and Drug Act contained food standardization provisions almost identical with Section 401 here involved.

The parallel provision to Section 401, appearing in the earlier statute, has been judicially interpreted. That section was involved in *Nolan* v. *Morgan*, 69 Fed. (2nd) 471 (C. C. A. 7), and in that case the Court of Appeals for the Seventh Circuit approved of the District Court's decision interpreting the words in the statute "promote honesty and fair dealing in the interest of the consumer" as meaning what this Court in *U. S.* v. *Antikamnia Chemical Co.*, 231 U. S. 654, said the earlier statute as a whole meant, namely (P. 665):

> "The purpose of the Act is to secure the purity of foods and drugs, and to inform purchasers of what they are buying."

The foregoing language is equally applicable to the present Food, Drug & Cosmetic Act. Therefore, no new question of scope or judicial interpretation is presented which would justify this Court's review of the present proceeding.

At page 13 of his petition, the Administrator further states the fallacy of his position when he says:

> "In most of the standards already promulgated, the Administrator has excluded or limited the quantity of one or more ingredients on the ground that their use

> would not promote honesty and fair dealing in the interest of consumers, although there was no evidence that the proposed ingredients were deleterious or that the proponents of these ingredients intended to misrepresent their products."

Correctly paraphrased, Section 401 quoted above says that *reasonable* definitions and standards of identity may be established by the Administrator when *such action* will promote honesty and fair dealing. It further says that he shall, to promote honesty and fair dealing, *designate* the optional ingredients to be named on the label. It is absurd to contend that salt, sugar, cream, chocolate, and other possible ingredients of a product must individually and *per se* promote honesty and fair dealing. On the other hand, Congress recognized that the nature of some ingredients might be such that honesty and fair dealing would be promoted by naming them on the label. The promotion of honesty and fair dealing relates to the propriety of taking action to establish a standard and to whether some ingredients should be named on the label; the test of the standard and of the ingredients of the standard is reasonableness. All that the Administrator had to do to promulgate a *reasonable* farina standard in accord with the purpose of the Act (purity of foods and inform purchasers of what they are buying) was to require that when farina is improved by the addition of Vitamin D, Vitamin D be named on the label.

2. The Administrator's second reason for urging the granting of the writ is that his finding that indiscriminate enrichment would tend to confuse and mislead consumers is clearly supported by substantial evidence. This is not a sufficient reason for granting the writ. After careful examination of the record, the Court of Appeals below found with respect to the possibilities of confusion that (Rec. 686):

> "There was no evidence in support of such possibilities and they are entirely speculative and conjectural."

A careful reading of the petition and of the record on this subject shows that the witnesses who speculated did so on the basis that confusion would result if there were a plurality of products on the market under the name "Enriched Farina," each, however, being enriched with different vitamin or mineral additions. But respondent does not market a product under the name "Enriched Farina" nor has it represented its product as "Enriched Farina." Respondent has for ten years been selling farina, not "Enriched Farina." Respondent has used the adjective "enriched" only as clearly and truthfully modifying the term "Vitamin D" in its designation "QUAKER FARINA Wheat Cereal Enriched With VITAMIN D." Thus it is apparent that respondent's offense under the Administrator's two standards would be in improving farina by the addition of a beneficial ingredient. It is the farina standard, not the enriched farina standard, that respondent violates,—violates by improving the product.

The realities of the situation must be considered. The weakness of the Administrator's argument with respect to indiscriminate enrichment causing confusion is clearly demonstrated by his admission that the sale of respondent's product has caused no confusion and has misled no one, not even petitioner's "ill-advised skeptic" or "the credulous" (Pet. 18). Yet the effect of the Administrator's two standards is to deprive the consumer of the opportunity of purchasing what he wants—respondent's product, improved nutritionally, an aid in overcoming a widespread Vitamin D deficiency, truthfully labelled and causing confusion to no one.

3. In presenting his third point the Administrator argues "*the ill-advised skeptic* will pay as much for plain farina as for the superior product, enriched farina (cf R. 413); *the credulous* can be persuaded to pay as much for one vitamin as for four (cf R. 177)" (Pet. 16). His regulations then are evidently only in the interest of "*the ill-advised*

skeptic" and "*the credulous.*" In other words, the regulations are not in the interest of reasonable, intelligent, average people constituting the vast majority of consumers.

On the subject of confusion the Court below had this to say (Rec. 686-7):

> "Furthermore, we should think that a product manufactured in accordance with the regulations in suit would tend to increase rather than retard confusion. This is especially true as to enriched farina. No such product has been sold heretofore under that designation. The manufacturer will be required only to label it "enriched farina," unless the option to add Vitamin D is exercised, in which case such addition must be stated. How the ordinary consumer will be informed so as to avoid confusion as to what is meant by enriched farina, its contents, or the benefits to be expected from its use, is a mystery which we are not able to fathom. How the contention that confusion is likely to result from a product, such as petitioner's, which truthfully informs the consumer as to what he is buying, can be reconciled with the contention that a product sold as enriched farina, without any further description, will lessen or avoid confusion, is beyond our comprehension."

4. The Administrator's fourth reason for urging the granting of the writ is that there is other evidence in the record supporting the exclusion of Vitamin D from the definition of farina (Pet. 18-19). This "other evidence" carries no weight whatsoever in view of the Administrator's own findings, based upon the *entire* evidence, of the existing widespread Vitamin D deficiency and the extensive use of respondent's product by infants and children, where that deficiency primarily exists (R. 617, 626). More importantly, it does not lie with the Administrator to argue such evidence in the face of his own recognition of Vitamin D as an optional ingredient in the standard for "enriched farina."

The record is clear and the Court below so found in stating that (Rec. 687):

> "• • • no claim is made of any relationship or co-action between Vitamin D and the other ingredients required in enriched farina."

CONCLUSION.

The effect of the Administrator's standards is to bar from the market and deprive the consumer of the opportunity of buying respondent's product, which in the language of the Court of Appeals is "admittedly a wholesome and healthful product", and which "has been sold to millions of consumers, without deception, fraud, or misrepresentation of any kind or character" (R. 683).

The Court below found that the Administrator, in so acting, exceeded his statutory authority and in substance said that regulations which prohibit the improvement of a product and deprive the public of an improved product which is honestly labelled, and which is neither adulterated nor diluted, do not promote honesty and fair dealing in the interest of consumers, and that such regulations are furthermore unreasonable and arbitrary and thus beyond the Administrator's statutory authority. Such being the case the Court of Appeals was clearly right in holding the farina and enriched farina standards invalid. There is no occasion for this Court to review that decision by the granting of the writ of certiorari. The petition, therefore, should be denied.

Respectfully submitted,

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On Writ of Certiorari to the United States Circuit Court of Appeals for the Seventh Circuit.

BRIEF FOR RESPONDENT.

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IN THE

Supreme Court of the United States

OCTOBER TERM, 1942

NO. 424

FEDERAL SECURITY ADMINISTRATOR,

Petitioner,

vs.

THE QUAKER OATS COMPANY,

Respondent.

On Writ of Certiorari to the United States Circuit Court of Appeals for the Seventh Circuit.

BRIEF FOR RESPONDENT.

INTRODUCTION.

This case arises under the Federal Food, Drug and Cosmetic Act of 1938. It is the first attempt by the government to make it a criminal offense to market a long established, widely used, *nutritionally superior* product, while permitting the sale of an *admittedly comparatively inferior* one.

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[1] Following the practice of petitioner's brief, we refer to him as the "Administrator" rather than as the "petitioner." Italics in this brief are supplied unless otherwise noted.

The *superior* product is farina with Vitamin D. The *relatively inferior* one is farina without Vitamin D. The case presents no element or suggestion whatsoever of adulteration, dilution, substitution, mislabeling, imitation, fraud, misrepresentation or deception. The extraordinary issue is presented of whether the Administrator may, through the device of establishing definitions and standards of identity under Section 401 of the Food, Drug and Cosmetic Act (21 U. S. C. A. 341), prevent respondent, a manufacturer of farina, from continuing a practice carried on by it for over 10 years of improving this food by the addition to it of nutritionally beneficial amounts of Vitamin D—an element which the Administrator, upon the evidence, found was widely deficient in the diet of infants and children.

Respondent has for over ten years manufactured and sold farina with Vitamin D added (R. 218). Millions of packages of respondent's products are sold yearly and by reason of its economy, the product is "widely available" and "known country wide" (R. 218). Farina is used largely as a breakfast food and as an ingredient of macaroni products (R. 207, 213; Finding 81, R. 626). It is extensively used as a cereal food for children, and in many cases is the only cereal food used during a period of their growth (R. 217, 272, 626). Respondent has been adding Vitamin D in carefully regulated amounts to its farina since April, 1932 (R. 218). Its product is labeled "Quaker Farina Wheat Cereal enriched with Vitamin D," or in some instances, "Quaker Farina enriched by the Sunshine Vitamin" and the mode of Vitamin D fortification or improvement of the product is described on the label (R. 218, 640).

Vitamin D is that vitamin which functions in regulating the metabolism of calcium and phosphorus in the body and is, therefore, concerned with the proper formation of bones

and teeth (R. 78). About 99% of the calcium in the body is contained in its skeleton (R. 78-9). Bones are living things like all other tissues of the body and there is a constant interchange of mineral salts contained therein (R. 85). Vitamin D facilitates the absorption of calcium and phosphorus from the alimentary tract (R. 78). The principal need for Vitamin D is in the infant and growing child—both large consumers of farina—in the prevention and cure of rickets and the building of strong bones and teeth (R. 80, 317-18, 361, 368-9). In the adult, deficiency of Vitamin D causes osteoporosis and perhaps certain other manifestations of improper calcium and phosphorus assimilation (R. 84-6).

Vitamin D, of all the known vitamins, is the one preeminently and notoriously deficient in the normal diet (R. 78-80, 82-4, 423). It is "the scarcest of the known vitamins" (R. 423). It is contained in substantial quantities in cod liver oil and in very small quantities in certain foods such as the yolks of eggs, milk and other dairy products (R. 79-80). It would take eight to twelve eggs per day to furnish an individual with a good supply of Vitamin D (R. 79). It would take 254 servings of white bread to supply the consumer with the Vitamin D equivalent of one-half a teaspoon of cod liver oil.

Sunlight as a source of Vitamin D is inadequate (R. 80, 423-33; Wisconsin Foundation Exs. S—BB, R. 529-53). Clouds, dust and smoke in the air act as screens to filter out the effective ultra violet rays from the sun just as does ordinary window glass (R. 425, Wisconsin Foundation Ex. T, R. 542). Studies on the number of tons of dust deposited per square mile during a year period show all the way from 349 tons per square mile to 1876 tons per square mile (R. 429-30, Wisconsin Foundation Ex. AA, R. 551). The number of clear days during the year when any sunshine at all is available is remarkably small (R. 426, Wisconsin Foundation Ex. V, R. 544-5).

Further, the sun's rays are effective in producing a Vitamin D effect only during certain short seasons of the year—particularly the summer months—and only during certain periods of the day—around noon when the sun is high (R. 426-7, Wisconsin Foundation Ex. W, R. 547). The clothing worn by civilized people today also prevents the sun's rays from being effective in producing any Vitamin D effect (R. 430-31). The ineffectiveness of sunlight and the widespread deficiency of Vitamin D are shown by a clinical study on the prevalence of rickets in the cities of Portland, Oregon, and San Diego, California (R. 428-9). The study, covering 1,000 children, showed that 95% of those in Portland and 73% of those in San Diego showed signs of rickets (R. 429).

The Court below summarized this evidence as follows (R. 682-3):

> "Vitamin D functions in regulating the metabolism of calcium and phosphorus in the body and is, therefore, concerned with the proper formation of bones and teeth. It is recognized as especially beneficial in the infant and growing child as a preventative and therapy of rickets and the building of strong bones and teeth. It is also an essential vitamin for adults. There is medical testimony to the effect that of all the known vitamins, it is the one most deficient in normal diet and should, therefore, be supplied in foods which are consumed regularly by the great mass of population, particularly those in the low income groups. While the Administrator found that milk was the most appropriate carrier for vitamin D, it is not disputed but that farina is also a proper carrier. Vitamin D in nature is found almost exclusively in sunshine and certain fish livers which are unavailable to humans in the normal diet. Therefore, as we understand, this vitamin is deficient in ordinary food products except when artificially supplied."

The Administrator found as a fact that (R. 617):

> "A deficiency of Vitamin D exists in large numbers of infants and children."

Also, in promulgating regulations regarding the labeling of products represented for special dietary use based upon their vitamin or mineral content under Section 403 (j) of the Act, the Administrator has found as a fact that the minimum daily requirement of Vitamin D for all persons, *irrespective of age*, is 400 U. S. P. units (6 Fed. Reg. 5923, Nov. 22, 1941).[2] This is the amount of Vitamin D supplied by a normal daily one ounce serving of respondent's farina (R. 218).[3]

Clinical tests upon respondent's product have shown excellent results in the improvement of health of children fed (R. 218).

In view of the scarcity of Vitamin D and the need for it in the diet, nutritionists agree that this vitamin should be added to foods which are consumed regularly by the great

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[2] Section 403 (j) of the Act (21 U. S. C. A. 343 (j)) reads:

> "A food shall be deemed to be misbranded—
>
> * * * * * *
>
> "(j) If it purports to be or is represented for special dietary uses, unless its label bears such information concerning its vitamin, mineral, and other dietary properties as the Administrator determines to be, and by regulations prescribes as, necessary in order fully to inform purchasers as to its value for such uses."

[3] "81. *The most common dietary deficiency diseases in infants* are scurvy, *rickets*, and nutritional anemia, *caused respectively by deficiencies of* vitamin C, *vitamin D*, and iron in human milk or in preparations used as substitutes for human milk, including, among others, cows' milk and evaporated milk in which the quantities of such substances have not been increased." (Finding of fact made by the Administrator pursuant to hearings under Section 403(j). 6 Fed. Reg. 5924, Nov. 22, 1941).

mass of our population, particularly those in the low income groups (R. 82-3, 182-3, 217-19, 555-6). This is because Vitamin D deficiencies are most widespread among people who (R. 428)

> "* * * cannot afford to buy Vitamin D in the form of antirachitic agents. * * * That is why the supplying of Vitamin D in some commonly consumed food on a communal scale will result in much better nutrition".

The slum baby, who may well receive no solid food except farina during its first few months of life (R. 217), will probably not get Vitamin D in the form of expensive cod liver oil, Viosterol or Vitamin D fortified milks because the poor mother can ill afford such products.

The scientists who testified at the hearing below agreed that farina is a proper and appropriate carrier for Vitamin D (R. 92, 189, 217-19, 555-6).[4] The reasons for this view are:

(1) Farina, by reason of its economy, reaches that group of people most likely to suffer from dietary deficiencies, i.e., the low income groups (R. 82-3, 182-3, 423, 427-8).

(2) Farina is widely consumed by infants and children, the age groups of the population suffering most from Vitamin D deficiencies and, therefore, most needing additional amounts of Vitamin D (Finding 35, R. 617; Finding 81, R. 626; R. 217, 272).

(3) From the physical standpoint, Vitamin D may easily be incorporated in farina, will remain stable therein and

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[4] The Administrator refers to testimony "against permitting the inclusion of Vitamin D in farina" (Adm. Br. 54). All of the testimony there referred to related to flour. Since flour is largely consumed by adul[ts] where the need for additional Vitamin D is nowhere near as great as in infants and children, some opinions were expressed that Vitamin D is not necessary in flour (R. 361, 386, 413, 497). *Not one witness testified specifically against the addition of Vitamin D to farina.*

is not destroyed by the heat of cooking processes (R. 92, 189, 217-9).

Milk and other dairy products contain only very small amounts of Vitamin D (R. 79). Milk, by reason of its calcium and phosphorus content (these minerals are made available in bodily metabolism by Vitamin D), is a good carrier of Vitamin D (Finding 40, R. 618). But in order for a consumer to get substantial quantities of this vitamin from milk, the producer must first go to the expense of putting it there and it is the consumers who need a low cost product who suffer most from Vitamin D deficiency (R. 427-8). The Administrator found that (R. 618):

> "The addition, however, of Vitamin D and calcium as optional ingredients to an enriched flour or enriched self-rising flour, will serve a useful purpose *for the benefit of persons who do not consume sufficient dairy products.*"

By Finding 83, the Administrator found the above quoted finding to be applicable to the "enrichment of farina" (R. 626). In view of the fact that farina, far more than flour, is widely consumed by those most apt to suffer from a Vitamin D deficiency, Finding 40 (R. 618) is even more applicable to farina than to flour.

Less than 6% of the milk sold is Vitamin D fortified (R. 79). Moreover, farina is almost always consumed with milk or cream and from this standpoint is a very desirable vehicle for Vitamin D. Further, one eminent scientist presented evidence that in his opinion the fortification of cereal products with Vitamin D (R. 556) "would probably do as much to make Vitamin D available to the public as fortification of milk with this essential." This opinion is based upon recent work in the chemistry of nutrition showing that most manufactured cereals today contain phosphorus in the form of phytic acid which is not

readiiy available to the human in the absence of Vitamin D (R. 555-6).

Under the Administrator's two standards—for farina and "enriched farina," respectively—respondent cannot lawfully continue the sale of its present product. Respondent has never marketed "enriched farina" or any product under that name, nor does the record show that anyone else has sold such a product. It is a fictitious product invented by the Administrator. It must be labeled "enriched farina" and its label need not disclose its required ingredients—Vitamin B_1, riboflavin, nicotinic acid and iron.

Respondent has sold farina. The Administrator's order prohibits respondent from improving its product by the addition of Vitamin D thereto by making it a criminal offense so to do. It is the farina standard, not the enriched farina standard, that respondent violates—*violates by improving the product*. Thus the Administrator's order prevents respondent from making its contribution to the reduction in the widespread deficiency of Vitamin D which the Administrator found exists "in large numbers of infants and children" (R. 617).

QUESTIONS PRESENTED.

We disagree with the statement of the "Questions Presented" in the Administrator's brief (p. 2). More properly stated the questions presented in this case are:

1. Whether the farina and enriched farina standards, considered either separately or together, are reasonable under Section 401 of the Act.

2. Whether the two standards are supported by substantial evidence in accordance with the requirements of Section 701 (e) of the Act.

3. Whether the two standards will accomplish the purposes of Section 401 of the Act.

In its presentation in the Court below, respondent treated the two standards separately whereas the Administrator attempted to treat them together and thus set off one standard against the other. The Court below agreed with respondent that the standards were properly treated separately (R. 683). However, the result is the same regardless of which treatment is followed, as the Court below pointed out (R. 683).

SUMMARY OF ARGUMENT.

I. The Administrator's Standards Are Invalid Because Unreasonable.

A. A definition and standard of identity to be valid must be reasonable.

The definitions and standards of identity for farina and enriched farina are unreasonable because

B. They impose upon the addition of Vitamin D to farina the unreasonable condition that Vitamin B_1, nicotinic acid, iron and riboflavin also be added thereto.

C. They deprive the consuming public of an established beneficial product and thus deprive infants and children, and particularly those in the low income groups, of much needed Vitamin D heretofore obtained in respondent's farina with Vitamin D. Thus they invade the consumer's fundamental right to good, wholesome food.

D. They increase, rather than diminish, the deficiency of Vitamin D which the Administrator found exists in "large numbers of infants and children in the United States" (R. 617).

E. They destroy an established business in a nutritionally improved and superior product and thus invade respondent's fundamental right to continue its business of

supplying the consuming public with a better food, as the Court below said, "without deception, fraud or misrepresentation of any kind" (R. 683).

F. They exclude Vitamin D from farina while permitting it in enriched farina.

G. They prohibit the nutritional improvement of a food product and thus place a ceiling over quality rather than a floor under it.

H. The Administrator's reasons do not support the two standards because

(1) The standards do not promote honesty and fair dealing in the interest of consumers.

(2) The Administrator's "instinct theory" is fallacious.

(3) The standards are unnecessary to facilitate enforcement.

(4) The difficulty in establishing the standards does not excuse unreasonable ones.

I. They do not conform with the principles and limitations of the Act.

II. The Standards Are Invalid Because Not Based Upon Substantial Evidence of Record.

A. A definition and standard of identity to be valid must be based upon substantial evidence.

B. The exclusion of Vitamin D from the farina standard is not supported by substantial evidence of record. There is no substantial evidence supporting the Administrator's finding of likelihood of consumer confusion. The evidence relied upon by the Administrator is speculative and conjectural. There is no evidence that respondent's practices have ever confused or misled anyone.

C. Respondent's contention that Vitamin D should be included as an optional ingredient in the farina standard is supported by substantial evidence. The Administrator ignored all of the evidence that Vitamin D should be included as an optional ingredient in farina, including evidence of

1. The deficiency of Vitamin D among infants and children, principal consumers of farina.
2. The value of Vitamin D in the diet in building strong bones and teeth and in the prevention and cure of rickets.
3. Opinion evidence of scientists that farina is an appropriate carrier for Vitamin D.
4. Respondent's prior commercial usage of Vitamin D in farina.

III. The Farina and Enriched Farina Standards Do Not Accomplish the Purposes of the Act.

A. The purposes of the Act are to secure the purity of foods and to inform purchasers of what they are buying.

B. The definitions and standards of identity for farina and enriched farina do not secure the purity of foods nor do they inform purchasers of what they are buying.

C. The definitions and standards of identity for farina and enriched farina promote dishonesty and unfair dealing.

IV. The Administrator Cites No Authority Justifying His Order Preventing the Sale of Farina Improved by the Addition of Vitamin D.

ARGUMENT.

I.

THE ADMINISTRATOR'S STANDARDS ARE INVALID BECAUSE UNREASONABLE.

A.

A Definition and Standard of Identity to be Valid must be Reasonable.

The requirement of reasonableness is explicit in the Act.[1] The language of the statute is so clear that citation of authorities would seem unnecessary. However, the authorities clearly support this view. In *Morgan* v. *Nolan*, 3 Fed. Supp. 143, affirmed by the Circuit Court of Appeals for the Seventh Circuit, 69 F. (2d) 471, a case arising under the previous Food and Drug Act, Judge Baltzell said (p. 145):

> "In order that such regulations may be valid, they must be reasonable and consistent with the law under which they are promulgated. *International Ry. Co.* v. *Davidson*, 257 U. S. 506, 42 S. Ct. 179, 66 L. Ed. 341; *Waite* v. *Macy*, 246 U. S. 606, 38 S. Ct. 395, 62 L. Ed. 892.
>
> The Food and Drug Act provides for the branding or labeling of food products, and defines the instances in which food shall be deemed misbranded. Title 21, §10, U. S. C. A. Prior to the amendment of this act in 1930, no authority was delegated to the Secretary of Agriculture to promulgate regulations for the standards of canned food products. Authority is given by

[1] Section 401. "Whenever in the judgment of the Administrator such action will promote honesty and fair dealing in the interest of consumers, he shall promulgate regulations fixing and establishing for any food, under its common or usual name so far as practicable, a *reasonable* definition and standard of identity, a *reasonable* standard of quality, and/or *reasonable* standards of fill of container; * * *."

such amendments to formulate such regulations. However, *such regulations must be reasonable and consistent with the law which authorizes them.* • • •

The regulations in question, requiring such labeling of plaintiffs food products, are unreasonable and inconsistent with the law under which they were promulgated, and are therefore invalid. *International Ry. Co.* v. *Davidson, supra.*"

In *A. E. Staley Mfg. Co.* v. *Secretary of Agriculture*, 120 F. (2d) 258, a case arising under the statute here involved, the court said (p. 260):

"In exercising the authority granted by the Act now involved, the Secretary must promulgate *reasonable* regulations that are in compliance with the Act, such as will promote honesty and fair dealing in the interest of consumers. *Morgan* v. *Nolan*, (D. C.) 3 F. Supp. 143, and *Nolan* v. *Morgan*, 7th Cir., 69 F. (2d) 471."

A determination of the reasonableness of any action of necessity involves an examination of the consequences of the action. If the advantages gained outweigh the detriment suffered, we say the action is a reasonable one. If, on the other hand, the detriments outweigh the advantages, the action is ordinarily characterized as unreasonable. Having in mind, then, the purposes of the Act and limiting the consideration to facts proved by substantial evidence of record, what are the consequences of the Administrator's standards?

B.

The Addition of the Required Ingredients is an Unreasonable Condition to the Addition of Vitamin D.

The effect of the farina standard, as the Administrator admits and as pointed out in his brief (Adm. Br. 2), is to bar from the market respondent's product, farina with

Vitamin D, by making it a criminal offense to market it. The Administrator argues, however (Adm. Br. 57-8), that respondent is not prevented from selling farina with Vitamin D but is only required to add certain minimum amounts of other ingredients (Vitamin B_1, riboflavin, nicotinic acid and iron), whereupon it may continue marketing the product. In other words, the Administrator's standards impose upon the manufacturer as a condition to adding Vitamin D to his product, the addition of these other four ingredients and the labeling of the product as "enriched."

The imposition of such a condition precedent to the addition of Vitamin D to farina is unreasonable. The Administrator devotes considerable space in his brief (Adm. Br. 18-21) to the proposition that Vitamin B_1, riboflavin, nicotinic acid and iron are beneficial ingredients. Respondent admits this, provided that such ingredients are added in sufficiently substantial amounts. Respondent would go further and say that there are many other nutrients which would be a beneficial addition to any food. Respondent can see no reason, however, for making it a crime to add any one of these beneficial ingredients to a food unless all of the others are also added (R. 165).[2]

There is no scientific basis for the requirement that before Vitamin D may be added to farina these other four ingredients must first be added. There is no showing in the record that there is any relationship between the four required ingredients of the enriched farina standard and Vitamin D. There is no co-action between Vitamin D and any of these required vitamin and mineral ingredients or

[2] Mrs. Potter, a consumer witness, testified (R. 165): "• • • some people may prefer to get their calcium and vitamins and iron in other ways, and I feel that *the consumer should be allowed to get what she wants to* • • •"

any combination thereof. If, for example, the evidence showed that Vitamin D was of no value except when *combined* with one or more of the required ingredients of the enriched farina standard, then there would be a reasonable basis for permitting the addition of Vitamin D to farina only if such other ingredients were also added. But there is no such showing in the record.

On this point the Court below said (R. 687):

> "We say it [the Administrator's order] is unreasonable for the reason that no claim is made of any relationship or co-action between Vitamin D and the other ingredients required in enriched farina. As a result, the consumer who is deficient in Vitamin D only, as is often the case, must buy a product containing vitamins and ingredients which he does not need, or does not want, in order to obtain the benefit of Vitamin D."

But the Administrator argues that the condition is not a burdensome one and feels that the respondent should go along with him on his program. He says (Adm. Br. 57-58):

> "Although the cost of vitamins may appear to be high in terms of dollars per pound (e.g. B_1 costs $700.00 per pound (R. 45, 65)), the minute quantities required results in an insignificant addition to the cost of production."

It is true that the "minute quantities required" may increase the cost but a fraction of a cent a pound. Multiply such fraction of a cent, however, by millions of pounds and the figure may represent the difference between profit and loss on a product. Moreover, to pass this additional cost on to the consumer would defeat the purpose of the Administrator's enrichment program, because it is ordinarily the low income consumer who particularly needs the

vitamins (R. 183).[3] As was said by Dr. Robert Williams (R. 409-410):

> "Obviously the poor of each country, and particularly of the United States, because that is what we are concerned with here today, who suffer most in general from vitamin deficiencies, the moment one adopts a scheme for handling a staple food which adds substantially to its cost, *one tends thereby to limit the consumption of that improved form of foods to the upper classes of the population, and to take it out of the hands of the lower classes of the population.*"

But, regardless of the dollars and cents involved, anything is expensive if its cost is out of proportion to its benefit. Respondent has shown elsewhere in this brief (*infra* p. 59) that the required minima of vitamins and minerals in enriched farina are so low as to provide no definite improvement in the diet.

Respondent concedes that if, under the protection of the Administrator's regulations, it wished to participate in a scheme to defraud the public by adding "minute quantities" of the required ingredients of the enriched farina standard, it could comply with that standard and would not be subject to criminal prosecution for misbranding. It could make substantial capital out of such compliance. It could with impunity advertise that its product was restored to whole wheat values without informing the public that the whole wheat values are so low as to effect no definite im-

[3] The evidence shows and the questions propounded by counsel for the Administrator indicate that *flour* products fortified with vitamins and minerals, substantially as outlined in the enriched farina standard, will sell and actually have sold for higher prices than the non-fortified flour products (R. 55, 90, 97, 165, 334-5, 335, 373, 490). Even the consumers who testified at the hearing below were not so optimistic as to anticipate that enriched flour would sell at no increase in price (R. 490). The Administrator also contemplates such an increase in price, as shown by his brief (Adm. Br. 58).

provement in their diet. It could claim that its product met U. S. standards. It could take advantage of the opportunities the standards afford it to work a fraud on the public. But certainly standards which require this are unreasonable.

Of course, respondent could go further than the standards require and could add a sufficient amount of the required ingredients to accomplish a real improvement of the product, but this would involve great additional expense and would be a major and not a minor alteration of its product.

Respondent submits that consumers have a fundamental right to obtain good, nourishing food for as low a cost as a manufacturer is willing and able to supply it. The Administrator is in effect saying to the mothers of infants and children:

> "For ten years you have been supplying your children with their Vitamin D requirements through the medium of farina fortified with Vitamin D. Henceforth, however, you will not be permitted to have Vitamin D through the medium of farina for your babies and children unless you also have, at increased cost to you, insignificant amounts of Vitamin B_1, riboflavin, nicotinic acid or nicotinic acid amide and iron. You must have these four additional ingredients even though your baby or child is getting ample amounts of those other four ingredients from other sources in his diet."

Respondent submits that it cannot be said to be reasonable to make it a criminal offense, punishable by fine and imprisonment, for a manufacturer *substantially* to improve a food product in one direction by the addition of one vitamin without simultaneously, at increased cost, *negligibly* improving that same product in four different directions by the addition of four separate, unrelated vitamins and minerals.

C.

The Standards Deprive the Consuming Public of an Established Beneficial Product.

As shown above, the effect of the two standards is to bar from the market farina with Vitamin D, by making it a criminal offense to market such product. Farina with Vitamin D added is better and more nutritious than farina as defined in the Administrator's farina standard.[4] Most of the millions of packages of farina sold by respondent during the past ten years has been consumed by infants and growing children (R. 626, 217). The effect of respondent's order is to deprive babies of Vitamin D in their farina, notwithstanding that the record shows, and the Administrator has found as a fact, that there is a Vitamin D deficiency in large numbers of infants and children. It is difficult to see how a standard of identity which reaches such a result can be said to be reasonable.

On this subject the Court below said (R. 687):

> "Another unreasonable result, so we think, is that by the exclusion of vitamin D from petitioner's product, many people will be deprived of this admittedly essential vitamin. This result is none the less real by reason of the suggestion that milk is the most appropriate carrier of vitamin D, and that the majority of consumers (infants and children) who use petitioner's product are also large consumers of milk. There might be merit to this suggestion but for the fact that vitamin D is not a substantial ingredient of milk or any other

[4] The most important use of Vitamin D is in the feeding of the infant and growing child for that vitamin is needed in the prevention or therapy of rickets and in the building of strong bones and teeth (R. 80, 217-18, 361, 368-9). "A deficiency of Vitamin D exists in large numbers of infants and children" (Finding 35, R. 617). Farina "is extensively used as a cereal food for children and in many cases is the only cereal food used during a period of their growth" (Finding 81, R. 626). It is "one of the first so-called solid foods to be fed to babies, starting off at the fourth or fifth month of the baby's life" (R. 217).

natural food product in ordinary use. *Thus, in order to obtain this essential vitamin in milk, it must be added thereto. Looking at the realities of the situation, we think this would mean that very few of the so-called low income group would receive sufficient vitamin D.* Too many of them, no doubt, are without the necessary amount of milk, much less milk to which this vitamin has been added. So, as a final result, the regulations are responsible for a situation whereby a consumer is precluded from obtaining vitamin D alone in connection with farina; he may get it in connection with enriched farina at the option of the manufacturer, or he may get it with his milk, provided he possesses the foresight to see that it is added thereto."

Depriving the consumer of an established beneficial product was recognized as unreasonable and not in the interest of the consumer in *Nolan* v. *Morgan*, 69 F. (2d) 471. That case arose under the McNary-Mapes amendment of July 8, 1930 (21 U. S. C. Section 10) to Section 8 of the U. S. Food and Drug Act of June 30, 1906. Under that amendment the Secretary of Agriculture was authorized to promulgate a "reasonable standard of quality, condition, and/or fill of container for each class of canned food as will, in his judgment, promote honesty and fair dealing in the interest of the consumer." He was further authorized to prescribe a form of label statement for canned food falling below the standard promulgated by him. In that case the standard set for canned peas was immature green peas, and the regulations required the appellee to label his peas, which were prepared from soaked dry ripe peas, with the legend "Below U. S. Standard. Low quality but not illegal. Soaked dry peas." The Court, finding that the appellee's product was a wholesome and nutritious food, held the regulations of the Secretary unreasonable, saying (pp. 473-4):

"* * * to say that canned ripe peas are an inferior grade of canned immature peas is, in our judg-

ment, at once illogical, unreasonable, and unfair * * *

> As stated in the amendment itself, the regulations to be made under it should 'promote honesty and fair dealing *in the interest of the consumer*,' and the Secretary of Agriculture is authorized, from time to time, to make modifications therein, 'as in his judgment, honesty and fair dealing *in the interest of the consumer* may require.' **It cannot be in the interest of the consumer to drive from the market this useful and cheaper product through branding it so the public will not buy it.**" (Italics are the Court's.)

If it is unreasonable to drive wholesome food from the market by a regulation requiring offensive labeling, it is manifestly unreasonable to drive similar food from the market by a standard of identity which absolutely prohibits the sale of the product because it is a better food than the one not recognized by the standard. The Administrator's standard is much more severe than was the standard of quality in the *Nolan* case. In that case the Secretary of Agriculture had the argument that the appellee could continue to market his product provided he employed the proper label, but in the respondent's case it cannot legally continue to market its farina no matter what kind of label it uses. The standard does not even permit it to use a "crepe" label.

Millions of packages of respondent's product are sold each year (R. 218). This is ample proof of the demand for respondent's product by the consumer. The people who are consuming these millions of packages are obtaining 100% of their minimum daily requirement of Vitamin D every day they consume a serving. It is certainly unreasonable to deprive these consumers of the product which they have shown during the past ten years that they desire and need and to which they are entitled. The language of Judge Baltzell in the lower court decision in the *Morgan*

case (3 Fed. Supp. 143, 145) is particularly applicable here.

> "The rapid increase in the amount of dry peas placed upon the market by plaintiffs within the past few years is ample proof of the demand for that particular product by the consumer. To require plaintiffs to comply with such regulations will not only seriously damage their business, *but will deprive the consumer of the product which he desires, and to which he is entitled.*"

D.

The Administrator's Order Will Increase the Present Deficiency of Vitamin D in Infants and Children.

As has been pointed out, the Administrator found that (R. 617):

> "A deficiency of Vitamin D exists in large numbers of infants and children."

The deficiency is greatest in families of low income who cannot afford to buy cod liver oil or other specifics (R. 83, 427-28). An example is disclosed by the spot map showing the distribution of cases on the rachitic studies through the city of Detroit in 1939 (R. 549). In reference to this, Dr. Scott pointed out that the disease was largely centered in the slum areas. He made clear the necessity for supplying Vitamin D in some commonly consumed food (R. 428). Farina is sometimes known as purified middlings (R. 220). It is cheap. Milk, also a good carrier, is relatively expensive.

At record 428-29 reference is made to studies of rickets conducted in Portland, Oregon, and in San Diego, California. These were taken from a publication, The American Journal of Disease of Children, of December, 1937 (R. 428). In Portland, of the children examined, 95% showed signs

of rickets; and in San Diego 73%. The failure of sunshine in San Diego would not seem to match the failure of sunshine among the tenements in our large industrial centers. Obviously, there is a plain necessity for Vitamin D in the cheaper available and used foods.

The effect of the Administrator's order in striking down respondent's farina with Vitamin D added, must be to increase, rather than to diminish, the deficiency of Vitamin D that even now, as the Administrator found, exists in large numbers of infants and children. It was not only wholly unnecessary to do this, but the order effecting such result is unreasonable. Shall this source of sufficient Vitamin D, to the extent of millions of packages per annum, be now removed because of an alleged confusion that in ten years' time has never occurred in a solitary instance, as far as this record shows?

E.

The Standards Destroy Respondent's Established Business in Farina Fortified With Vitamin D.

Respondent has spent ten years in building up a business in the improved food product, farina with Vitamin D (R. 218). The product has been made widely available (R. 218). It is submitted that any definition and standard of identity which destroys an existing business in an established beneficial food product is on its face not "reasonable" within the meaning of the Act. In *Twin City Milk Producer's Assn., et al. v. McNutt*, 122 F. (2d) 564, the Circuit Court of Appeals for the Eighth Circuit had before it on review a definition and standard of identity promulgated by the Administration for "dried skim milk." The petitioner in that case attacked the name referred to in the standard as being unreasonable, urging in lieu thereof the name "dry

milk solids not over 1½% fat." In sustaining the Administrator on that phase of the case, the court said (p. 568):

> "While he (the Administrator) would have *no right to adopt a designation for the purpose of destroying trade in a legitimate food product*, there could ordinarily be no arbitrariness involved in using the common or usual name of such a product for regulation purposes."

So here, paraphrasing the Court's language, the Administrator had no right to adopt a standard for the purpose of *or with the necessary effect of* destroying trade in the respondent's legitimate food product.

That a definition and standard of identity for a food which destroys a going business in a legitimate, wholesome food product is not contemplated by the Act is also shown by the Senate Committee report on the bill eventuating into the Act. That report stated:

> "This bill has been prepared with three basic principles in mind; first, it must not weaken the existing laws; second, it must strengthen and extends the law's protection of the consumer; and, third, *it must impose on honest industrial enterprise no hardship which is unnecessary or unjustified in the public interest.*" Senate Report No. 152; 7th Congress, March 8, 1937.

The Administrator argues that it is immaterial that a particular manufacturer must change his methods or product or even that some products may be driven from the market (Adm. Br. 57). In support of this statement respondent cites a number of cases which, however, as will be pointed out in this brief (*infra* pp. 33-4), involve the question of whether Congress or a state legislature may do

the acts complained of.[5] What is reasonable for Congress or state legislature may not be reasonable for administrative action and is not reasonable in this case, in view of the declared purpose of the Act.

Respondent cites the case of *Houston* v. *St. Louis Independent Packing Company*, 249 U. S. 479, 484 (Adm. Br. 47-58), as demonstrating that an administrative agency may bar a food from the market. Examination of that case, however, reveals that it was a case of *dilution* of sausage by the addition of cereal. Surely the Administrator does not object to Vitamin D on the ground that it dilutes farina. So also examination of the case of *United States* v. *Carolene Products Co.*, 304 U. S. 144, 149 (Adm. Br. 57) reveals that it involved the adulteration of milk by the substitution of cocoanut oil for milk fat.[6] Admittedly respondent does not claim that farina is being adulterated by the addition of Vitamin D.

The Administrator's position that the fact that respondent's product has been accorded consumer acceptance and approval should not be considered is strikingly inconsistent with the Administrator's argument in *Staley Manufacturing Company* v. *Secretary of Agriculture*, 120 F. (2d) 258, that there the petitioner's product (corn syrup) was not entitled to be named as an optional ingredient in sweetened condensed milk *because it had no prior commercial use.*

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[5] *Mugler* v. *Kansas*, 123 U. S. 623, 628, 633; *Powell* v. *Pennsylvania*, 127 U. S. 678, 683, 685; *Hebe Co.* v. *Shaw*, 248 U. S. 297, 302-303; *United States* v. *Carolene Products Co.*, 304 U. S. 144, 151.

[6] The Circuit Court of Appeals, speaking of the Carolene Products case, said (R. 687-8): "The court, in commenting upon the Congressional hearings, on page 149 of 304 U. S., page 781 of 58 S. Ct., said: '• • • Both committees concluded, as the statute itself declares, that the use of filled milk as a substitute for pure milk is generally injurious to health and facilitates fraud on the public.'"

F.

It Is Unreasonable to Exclude Vitamin D as an Optional Ingredient from Farina and Permit It as an Optional Ingredient in Enriched Farina.

It has heretofore been pointed out that there is no coaction or joint action between Vitamin D and the required ingredients Vitamin B_1, riboflavin, nocotinic acid and iron of the enriched farina standard. Consequently, if it is reasonable to permit Vitamin D to be added to the product enriched farina as an optional ingredient, it is on the face of it unreasonable to exclude Vitamin D as an optional ingredient from the product farina.

The Administrator's principal point for the exclusion of Vitamin D from farina is the argument hereinafter answered that consumers will be confused and misled by permitting such practice. It will be shown that no one has ever been confused or misled by respondent's practice and that there is no evidence of any likelihood or even possibility of such confusion occurring (*infra* pp. 40-46). If such confusion does or will exist as a result of adding Vitamin D to farina, it would seem that exactly the same confusion would occur as a result of the addition of Vitamin D to so-called enriched farina. If the Administrator's theory on confusion is right, why does he permit Vitamin D *or anything else optionally* to be added to his "enriched farina?" This will promote confusion just as much as the addition of Vitamin D to farina. In both cases, the only way the consumer will know whether or not Vitamin D is in the product will be by the *label declaration*. If the consumer cannot read or understand what he reads; he will never know; if he can read and understand, and does so, he will know *in either case*.

The Standards Prohibit the Improvement of Farina.

Another unreasonable consequence of the farina standard is that it puts a ceiling over quality rather than a floor under it. In establishing his standard of *identity* the Administrator has established an unreasonable standard of *quality*. The result of his order is that any manufacturer who attempts to make his product better than that of his competitor subjects himself to criminal prosecution unless his improvement coincides exactly with the improvements specified for him by the Administrator. Clearly such a result was not intended by the Act. Clearly the standards reaching such a result are not reasonable.

But the Administrator argues that the effect of the decision below is to require every definition and standard of identity to include a blanket clause permitting any non-deleterious variation which is disclosed by the label (Adm. Br. 31, 42).[7]

This conclusion does not follow. Obviously the allowance of the addition of all non-deleterious ingredients, regardless of whether they are of added benefit to the product, would result in dilution of the product. For instance, water is a non-deleterious ingredient, yet no one has suggested that the addition of water to a standardized product be permitted on this account. The Administrator is, and should be, permitted to prevent dilution.[8] He may do so by the

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[7] This is part of Administrator's general argument to the effect that the standards are intended to be exclusive (Adm. Br. 39-45). He says (Adm. Br. 33): "This power to permit optional ingredients cannot be construed as an obligation to permit any disclosed non-deleterious addition, or, in other words, to exclude only deleterious or concealed ingredients, for to do so renders identity standards nugatory."

[8] See respondent's discussion of *Houston v. St. Louis Packing Co.*, 249 U. S. 479 (*supra* p. 24).

simple means of restricting optional ingredients to those which will *improve* the product.

Respondent has not asked for the inclusion of Vitamin D as an optional ingredient in farina merely because it is non-deleterious, nor even because it is a beneficial ingredient. Its inclusion is requested because its addition *makes the finished product a better product.*

Moreover, Vitamin D is not merely an idly "suggested" addition. It is not a theoretical improvement. It is an accomplished improvement with over ten years of commercial practice behind it. Its inclusion was supported by substantial proof of record at the public hearing held by the Administrator for the express purpose of receiving such proofs. Of what purpose is the public hearing if the Administrator is permitted to ignore the evidence there adduced? As was said in *A. E. Staley Mfg. Co.* v. *Secretary of Agriculture*, 120 F. (2d) 258, 261:

> "Certainly the right to present evidence is a barren one if the trier of fact fails to consider it."

It is submitted, therefore, that neither the decision of the Circuit Court of Appeals nor respondent's contention implies the conclusion that all non-deleterious ingredients would have to be included. What the Circuit Court of Appeals did say and what respondent now says is that the standard for farina is unreasonable in excluding Vitamin D in view of the evidence in the case.

B.

The Administrator's Reasons for the Exclusion of Vitamin D from Farina Are Untenable.

The above examination of the consequences of the Administrator's standards has demonstrated that they impose an unreasonable condition on the addition of Vitamin D to

farina, that they will deprive the consuming public of the established beneficial product, that they will increase the Vitamin D deficiency in infants and children, that they will destroy respondent's established business in its farina product, and that they will prohibit improvement of the standardized product. What advantages then does the Administrator claim which will outweigh these detriments and make the standards reasonable?

1. *Honesty and fair dealing.*

The Administrator claims that the standards will promote honesty and fair dealing. Respondent, however, will demonstrate (*infra* pp. 56-62) that exactly the reverse will be true and that the standards will in fact promote dishonesty and unfair dealing.

2. *The instinct theory.*

The Administrator contends that Vitamin B should be excluded from farina because it does not occur in significant quantities in the whole wheat berry (Adm. Br. 20). Thus he justifies his enriched farina standard requiring Vitamin B_1, riboflavin, nicotinic acid and iron on the ground that they are found in the whole wheat berry (Adm. Br. 55). He claims that his standards are not artificial because they are "an accommodation to existing natural, historical, and dietary phenomena" (Adm. Br. 55). Apparently the genesis of the idea that enrichment of farina should be limited to enrichment in those nutrients contained in the original wheat berry is the "instinct theory" of Dr. Russell W. Wilder. He said (R. 102):

> "It is not impossible that subconsciously when we need Vitamin A or one of the other fat-soluble vitamins, we turn to a fat to get it. I cannot offer proof of that, but it is a suggestion, and that when we subconsciously have a feeling that we want some Vitamin C, we don't

> turn to fat for Vitamin C, we subconsciously ask for an orange, or some tomato juice; and likewise when we subconsciously feel the need for any part of the Vitamin B complex, particularly for the thiamin of the Vitamin B complex, we turn to the cereal grains."

This theory would lead logically to the surprising conclusion that when one needs Vitamin D, he would experience a subconscious seeking for cod liver oil. But perhaps this unrealistic conclusion has been avoided by Doctor Wilder's admission on cross-examination that the human animal instincts have undergone such serious deterioration that instinct could probably not be relied upon (R. 112).

The fallacy of the instinct theory and of the Administrator's argument was pointed out by Doctor Sherwood. He said (R. 146):

> "Obviously, the wheat kernel is produced to propagate the wheat plant. * * * And the mere fact that it has certain of these vitamins and minerals present in certain proportions does not indicate a proper balance for us."

He also said (R. 147):

> "* * * the lumberman saws the tree to fit the house and doesn't build the house to fit the tree."

The theory was entirely exploded by the Administrator's own witness, Doctor Nelson, Chief of the Vitamin Division of the Food and Drug Administration. He pointed out that if instinct could be depended upon, people would subconsciously choose whole wheat bread, and the whole Vitamin B enrichment program would be pointless (R. 182).

Clearly the ingredients of the standardized food should be determined by the necessity for those ingredients in the diet, with special consideration as to how that food fits into the diet. The vitamins or minerals contained by the food in its natural state have nothing whatsoever to

do with the question. Respondent adds Vitamin D to farina because there is a marked deficiency of Vitamin D in the diets of most people, and particularly in the diets of infants and children. Its function is to promote the assimilation by the body of calcium and phosphorus, which are contained in other foods, particularly in milk, with which farina is usually consumed. "* * * the only natural food designed for human nutrition is mother's milk" (R. 45). Accordingly, blind loyalty to existing natural phenomena cannot be considered reasonable.

Respondent has no objection to the inclusion of the Vitamin B group as additional *optional* ingredients in the farina standard. This group is composed of beneficial ingredients, and if the Administrator is satisfied that substantial evidence supports their inclusion as optional ingredients, he should so provide. The record shows that a deficiency of one of the Vitamin B complex is usually accompanied by deficiency in the others (R. 366, 388). Accordingly, respondent would be in favor of a ruling that no member of the Vitamin B complex should be added unless other members of that group are also added. This fact has nothing to do with Vitamin D. Vitamin D does not exist to an appreciable extent in the normal diet. Accordingly, a Vitamin D deficiency may occur—and in modern city life with its smoke, dust, and artificial light does occur—in spite of a well balanced diet. There is no coaction between Vitamin D and the Vitamin B complex (*supra* pp. 14-15). They are independent. There is no chemical, nutritive, or other reason why the addition of one should be a condition precedent to the addition of another.

3. *Facility of enforcement.*

The Administrator argues that the standards must be exclusionary or they will be valueless (Adm. Br. 30-45).

With this respondent has agreed (*supra* pp. 26-7).[9] The Administrator says that this is necessary to permit the standards to be enforced to prevent dilution or adulteration (Adm. Br. 36-40). Again respondent agrees.[10] But all of this gives no support to the Administrator's denial of the right of consumers to have farina improved with Vitamin D. The provision for the inclusion of Vitamin D as an optional ingredient would not hinder the Administrator's enforcement of the law to prevent dilution or adulteration. No one will dilute or adulterate farina worth a few cents a pound with vitamins worth hundreds of times as much.

4. *Difficulty in drawing the line.*

The Administrator says that his problem is one of where to draw the line and that in testing the reasonableness of the line which is drawn, the issue cannot be whether the line may have been drawn at some other point (Adm. Br. 53). But this line-drawing cannot be treated as casually as that.[11] There are millions of consumers entitled to fair consideration and respondent has a business at stake. Respondent, at not inconsiderable cost in time, effort, and money sent witnesses to the Administrator's hearings and proved its case. If the line is drawn to exclude respondent's

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[9] If the farina standard were not exclusionary then obviously respondent could add Vitamin D to its farina and the present controversy would never have arisen.

[10] The Administrator cites *U. S. v. Ten Cases, More or Less, Bred Spred*, 49 F. (2d) 87, which was a case of dilution. The Administrator should, and does, have the right under the Act to prevent dilution.

[11] The Administrator says: "Reasonable men basing their action on the same facts and findings could arrive at entirely different regulations, none of which could be properly characterized as arbitrary, whimsical, or unreasonable" (Adm. Br. 54). As is pointed out (*infra* p. 34) legislative acts are valid only unless "arbitrary" or "whimsical," but the Administrator is not given such a latitude. He must make his regulations reasonable (*supra* pp. 12-13).

product and there is not substantial evidence to support such action as reasonable, the standards should be set aside. The Administrator is charged with quasi-judicial functions and must perform his duties with care and conscientious consideration for the rights involved. As was said by Chief Justice Hughes in *Morgan* v. *United States*, 304 U. S. 1; 22:

> "The maintenance of proper standards on the part of administrative agencies in the performance of their quasi-judicial functions is of the highest importance and in no way cripples or embarrasses the exercise of their appropriate authority. On the contrary, it is in their manifest interest. For, as we said at the outset, if these multiplying agencies deemed to be necessary in our complex society are to serve the purposes for which they are created and endowed with vast powers, they must accredit themselves by acting in accordance with the cherished judicial tradition embodying the basic concepts of fair play."

But the Administrator says that "presumably, if Vitamin D were entitled to be included as an optional ingredient, a multitude of other non-deleterious ingredients has equal claim to optional inclusion" (Adm. Br. 54n).[12] The Administrator does not contend that this statement is supported by the record. If it is, however—if substantial evidence of record indicates that other ingredients are entitled to the same treatment as Vitamin D—then the Administrator should have included them and his exclusion of them should have been corrected if appeal had been taken from his order within the proper time. Respondent submits that *if there is substantial evidence that an ingredient will improve the product, it is unreasonable to exclude it.*

[12] It has been pointed out that the right of Vitamin D to be included as an optional ingredient is not based upon the mere fact that it is a non-deleterious ingredient (*supra* p. 27). That right is based upon improvement of the product, consumer need and prior use.

Reviewing, then, the consequences of the Administrator's standards, what is the result? The detriments are manifest. The standards impose an unreasonable condition to the addition of Vitamin D. They will deprive the consuming public of an established beneficial product. They will increase an existing Vitamin D deficiency. They will destroy respondent's established business and its product. They will prohibit improvement of the food. Against these detriments the Administrator claims outweighing advantages. He says his standards are consistent with an instinct theory which has been shown to be fallacious by testimony which the Administrator himself adduced. He claims they will facilitate enforcement, which has been shown to be untenable. And finally he has confessed weakly to a difficulty in drawing the line. It is submitted that the detriments suffered by far outweigh the advantages claimed. The standards are therefore unreasonable.

I.

The Administrator's Determination of Reasonableness Is Limited by the Principles and Limitations of the Act.

The word "reasonableness" is, of course, a relative term. It involves a consideration of the purposes to be accomplished. It also involves a consideration in the light of certain given facts. Accordingly, the determination of reasonableness of the standards in question is interdependent with the consideration of the purpose of the Act and of the substantial evidence upon which the determination must be made. These two subjects will hereinafter be considered (*infra* pp. 51-64; 38-51).

It is submitted that the Administrator, in claiming wide latitude in the determination of reasonableness, has lost sight of the other requirements of the Act. In support of his claim of unrestricted discretion in the determination

of reasonableness, he has cited a number of cases (Adm. Br. 57).[13] Without exception, however, these cases relate to the constitutional powers of Congress or state legislatures to enact the statutes in question. Of course, the test applied in these cases was the test of reasonableness, but the Administrator cannot claim the latitude which Congress enjoys in making the laws. If the Administrator's power can be broad as that of Congress, then unlawful delegation of power would never be a valid objection to any legislation.

The power of Congress or of a state legislature to determine reasonableness is very broad. In *Southern Garment Manufacturers Association* v. *Fleming*, 122 F. (2d) 622, 632, the Court said:

> "Now it should be remembered that the legislative could meet and without any consideration or deliberation put a and b into class m and c into class n. And when the problem got to the courts the issue would still be, is the classification arbitrary, or is there any relation between method and end, and not is the grouping wise."

In *Hebe Co.* v. *Shaw*, 248 U. S. 297, 303, Justice Holmes, speaking for this Court, said:

> "The inquiry must be whether, considering the end in view, the statute passes the bounds of reason and assumes the character of a merely arbitrary fiat."

In *Powell* v. *Pennsylvania*, 127 U. S. 678, 684, this Court quoted with approval from its opinion in *Sinking Fund Cases*, 99 U. S. 700, 718, as follows:

> "Every possible presumption is in favor of the validity of a statute, and this continues until the contrary is shown beyond a rational doubt."

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[13] *Mugler* v. *Kansas*, 123 U. S. 623, 628-633; *Powell* v. *Pennsylvania*, 127 U. S. 678, 683-684; *Hebe Co.* v. *Shaw*, 248 U. S. 297, 302-303; *U. S.* v. *Carolene Products Co.*, 304 U. S. 144, 151.

What, then, is the difference between the Administrator's power to determine reasonableness and that of Congress? In *Panama Refining Co.* v. *Ryan*, 293 U. S. 388, 421, this Court, holding that section 9 (c) of the National Industrial Recovery Act provided for an unlawful delegation of power, said:

> "The Constitution has never been regarded as denying to the Congress the necessary resources of flexibility and practicality, which will enable it to perform its function in laying down policies and establishing standards; while leaving to selected instrumentalities the making of subordinate rules *within prescribed limits* and the determination of facts to which the policy as declared by the legislature is to apply. • • • But the constant recognition of the necessity and validity of such provisions, and the wide range of administrative authority which has been developed by means of them, *cannot be allowed to obscure the limitations* of the authority to delegate, if our constitutional system is to be maintained."

The Court then reviewed a number of cases to show that Congress must set up "primary standards" or "intelligible principles," and referring to the statute under consideration by it, said (p. 430):

> "• • • Congress has declared no policy, has established no standard, has laid down no rule. There is no requirement, no definition of circumstances and conditions in which the transportation is to be allowed or prohibited."

In *Schechter Corp.* v. *United States*, 295 U. S. 495, 537-538, this Court said:

> "• • • Congress cannot delegate legislative power to the President to exercise an unfettered discretion to make whatever laws he thinks may be needed or

advisable for the rehabilitation and expansion of trade or industry."

Respondent has not argued that the Federal Food, Drug and Cosmetic Act makes an unconstitutional delegation of authority to the Administrator. The reason that this argument has not been made is that respondent recognizes that Congress has attempted in the Act to preclude the charge of unlawful delegation, by carefully declaring the policy of the Act and by prescribing standards, principles, and limitations governing the exercise of power by the Administrator. The policy of the Act is to "promote honesty and fair dealing in the interest of consumers." As was said in the case of *A. E. Staley Mfg. Co.* v. *Secretary of Agriculture*, 120 F. (2d) 258, this means that the purpose is to secure purity of foods and to inform purchasers of what they are buying. The aim of *purity* and *information*, then, constitutes the policy, the principle, the standard of the Act.

But there are limitations too. The Administrator is not given the "unfettered discretion" condemned in the *Schechter* case. He must "hold a public hearing" after "appropriate notice"; his order must be based only on "substantial evidence of record," and must set forth "detailed findings of fact."

The right of Congress to legislate is not so restricted. Legislation must be reasonable, but its reasonableness is not measured in the light of the above limitations or of predeclared policy.

The Administrator must confine his activities to the promotion of the policy of the Act as above defined. Within the limitations set forth, he may do three things: (1) Fix reasonable definitions and standards of identity; (2) fix reasonable standards of quality; (3) fix reasonable stan-

dards of fill of container. For what purpose may he do these things? He may fix definitions and standards of identity so that consumers will get what they pay for, so that sellers won't lie about their products. He may fix standards of quality so that sellers will not dilute or adulterate their products. He may fix standards of fill of container so that sellers will not sell twelve ounces in a container appearing to hold a pound.

These aims are commendable. They are within the power grant of the Act. If the Administrator's action in respect to farina goes beyond this, his order is invalid. Respondent is as anxious to be protected against cheating competitors as is any other honest manufacturer. But respondent cannot agree that the Administrator has the power to bar from the market any food which he, in his uncontrolled discretion, may see fit to outlaw, without regard to whether that food is wholesome or deleterious, and then to seek to justify his action on the ground that Congress could do this.

The Congressional Act is fair. But the Administrator in his determination of reasonableness may not disregard its declared policy; its principle, its standards, and its limitations by the assertion of powers tantamount to those possessed by Congress. If he does so, he construes the Act to an unconstitutional result. It is not enough that legislation contain the requisite language to make it constitutional. The courts also have a duty to administer it to a constitutional result. *Sawn* v. *Williams*, 273 Mich. 402, 263 N. W. 407, 409. Otherwise the Act would be invalid as an unconstitutional delegation of powers. This Court has said that if a doubt arises as to a constitutional point, that construction should be adopted which avoids the doubt. *U. S.* v. *Shreveport Grain & Elevator Co.*, 287 U. S. 77, 82; *Lewellyn* v. *Frick*, 268 U. S. 238, 251, citing *Panama R. R. Co.* v. *Johnson*, 264 U. S. 375, 390.

Respondent submits that the Act does not give to the Administrator the uncontrolled discretion in the determination of reasonableness which he claims. The distinction between "reasonable" as applied to legislation and "reasonable" as applied to the Administrator's order may not be overlooked. As was said by the Court below, in commenting upon *U. S. v. Carolene Products Co.*, 304 U. S. 144 (R. 688):

> "Furthermore, the court in the Carolene case was dealing with the power of Congress, while here we are considering the authority which Congress has conferred upon the Administrator, and the reasonableness of his action."

II.

THE STANDARDS ARE INVALID BECAUSE NOT BASED UPON SUBSTANTIAL EVIDENCE OF RECORD.

A.

A Definition and Standard of Identity to be Valid Must Be Based upon Substantial Evidence.

Section 701 (e) of the Act provides in part as follows (21 U. S. C. A. 371 (e)):

> "The Administrator shall base his order only on substantial evidence of record at the hearing and shall set forth as part of the order detailed findings of fact on which the order is based."

The requirement of "substantial evidence" is not new in administrative law. The term in general has been said to mean such relevant evidence as a reasonable mind might accept as adequate to support a conclusion. It must be enough to justify, in a jury trial, a refusal to direct a

verdict when the conclusion sought to be drawn from it is one of fact for the jury.[1]

Manifestly, when the statutory requirement of substantial evidence in support of the order is not met, the order is invalid. And if the only substantial evidence adduced is contrary to the order, it is even more clear that the order cannot be sustained. For evidence cannot be ignored. In this connection, in the case of *A. E. Staley Manufacturing Company* v. *Secretary of Agriculture*, 120 F. (2d) 258, the Court said (p. 261):

> "The petitioner adduced evidence at the hearing, which is undisputed, which appears to constitute 'substantial evidence of record,' but which the Secretary of Agriculture ignores completely in its order. The statute provides that the Secretary "shall base his order only on substantial evidence of record at the hearing and shall set forth as part of the order detailed findings of fact on which the order is based' 21 U. S. C. A. 371 (e).
>
> "In effect petitioner complained that the administrative fact finder did not consider the evidence in question. *Certainly the right to present evidence is a barren one if the trier of fact fails to consider it. Morgan* v. *United States*, 298 U. S. 468, 304 U. S. 1."

Accordingly, in the instant case, if any part of the standard, including the omission of any suggested optional ingredient, is not supported by substantial evidence, the standard is invalid. And if substantial evidence was adduced to support the inclusion of an optional ingredient, the standard is even more clearly invalid, if it fails to in-

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[1] *N. L. R. B.* v. *Columbian Enameling Company*, 306 U. S. 292, 299-300 (1939); *Consolidated Edison Company* v. *N. L. R. B.*, 305 U. S. 197, 229 (1938); *Hamilton Brown Shoe Company* v. *N. L. R. B.*, 104 F. (2d) 49, 52 (8 C. C. A., 1939); *N. L. R. B.* v. *Louisville Refining Company*, 102 F. (2d), 678, 680 (6 C. C. A. 1939); *Montgomery Ward & Co.* v. *N. L. R. B.*, 107 F. (2d) 555, 558 (7 C. C. A. 1939); *Cupples Co., Mfrs.* v. *N. L. R. B.*, 106 F. (2d) 100, 114 (8 C. C. A. 1939); *N. L. R. B.* v. *Empire Furniture Corp.*, 107 F. (2d) 92, 95 (6 C. C. A. 1939).

clude such optional ingredient—if the Administrator merely ignored the testimony on that question.

B.

Exclusion of Vitamin D from the Farina Standard is not supported by Substantial Evidence of Record.

Apparently the Administrator excluded Vitamin D from the standard for farina and included it in the standard for enriched farina for two reasons. The first of these reasons seems to be a vague feeling that the proper standard of enrichment is the standard set by nature in the formation of the wheat berry itself (Adm. Br. 20-22, 55-56). The fallacy of this reasoning is discussed elsewhere in this brief (*supra* pp. 28-30). And, of course, the Administrator himself has admitted the fallacy by including Vitamin D in the enriched farina standard, thereby abandoning his "restoration" theory of enrichment and admitting the propriety of the addition of Vitamin D (R. 637-8).

The other basis for relegating Vitamin D to the artificial enriched farina standard is the claim of the Administrator that optional[1] enrichment would tend to confuse and mislead consumers. This claim is based upon findings 36, 37, and 39, which in turn are based upon testimony relating to flour. The Administrator attempted to make these findings apply to farina by the easy process of "incorporation by reference" (Finding 83, R. 626). But in so doing he

[1] The Administrator refers to "partial" enrichment. The word "partial" is confusing. Respondent believes that the standard should require a *quantitative* minimum of any vitamin that is added; i.e., if Vitamin D is added, it should be added in such quantity as will effect a definite improvement in the product (see respondent's argument that the Administrator's standard for enriched farina is a potential instrument of fraud because its minima are too low, *infra* pp. 59-61). Respondent objects to a requirement of *qualitative* minima, i.e., the contention that B_1, etc., must be added if D is to be added. Qualitative enrichment is always "partial," because no one expects to make of farina a perfect food containing all the nutrients required by the human body. Hence the Administrator's enriched farina standard specifies "partial" enrichment both quantitatively and qualitatively.

ignored the fact that there was no evidence to support such findings as to farina.

And even as to flour, the testimony is no support whatsoever for the Administrator's findings of a likelihood of confusion. The Administrator's numerous references to the record on this point (Adm. Br. 23-26), may create the impression that there was testimony in support of these findings. Of the four "consumer representatives" whose testimony was cited by the Administrator (Adm. Br. 23), *none testified that optional enrichment would cause confusion*. One testified that she opposed grouping differently enriched flours *under one name*, and that the adding of any one or more vitamins to a flour *would not cause confusion if shown on the label*, thus supporting respondent's position and commercial practices.[2]

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[2] This witness was Miss Ross whose testimony is heavily relied upon but incompletely quoted by the Administrator (Adm. Br. 25-26). In expressing her opinion on possible consumer confusion Miss Ross, as her testimony on pages 496-97 of the record clearly shows, was objecting to the grouping under one common name, such as "fortified flour" or "enriched flour," of a multitude of products each fortified with different vitamins or minerals and each containing perhaps different amounts of such vitamins or minerals. Referring to a flour to which, for example, only one vitamin had been added, she said (R. 496):

> "• • • flour with only one of these factors should we feel not be permitted to make use of the term 'fortified' or whatever term is applied to flours."

Her testimony affirmatively shows, however, that she saw no possibility of consumer confusion in the enrichment of foods with single vitamins, if such fortification was properly indicated on the label. She testified that the added ingredients should be listed (R. 497):

> "on a less fortified product, which would not use that one word [such as "fortified" or "enriched"], *but would have some other indication of what other ingredients had been added*."

Further, when Miss Ross testified regarding the consumer's "truly difficult position" (Adm. Br. 26), she was discussing the desirability of adopting *uniform nomenclature* for the various vitamins, not their use in the enrichment of foods (R. 492). This has no bearing on the question of possible confusion by the *fact* of optional enrichment.

Another expressed her "fear," *not of the addition of a single vitamin, but of the Administrator's restoration theory* (R. 116).[3] Another, representing the American Association of University Women, an organization of 68,000 consumers, wanted labeling which would tell her what she would get, so that she could take her choice (R. 164).[4] She testified (R. 165):

> "There are very definite advantages to a reinforced flour, *but some people may prefer to get their calcium and vitamins and iron in other ways, and I feel that the consumer should be allowed to get what she wants to* . . . ."

The last witness also wanted identification (R. 175).[5]

The Administrator also cited the testimony of two "disinterested scientists" (Adm. Br. 23). The first is Doctor Wilder, the proponent of the "instinct theory" (*supra* pp. 28-30). We find no expression of fear of confusion in his cited testimony. The other is Doctor Williams who suggested that if a vitamin is added, it should be added in sufficient amounts (R. 409).[6]

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[3] "I fear that if Vitamin B_1 and other substances present in whole wheat are added to wheat flour for general consumption, we shall witness a tremendous advertising campaign about the marvelous effects of these elements, which will make people overconfident about the value of these products and cause them to forget that *whole wheat flour is still the only complete flour.*"

[4] Respondent gives her such labeling. The Administrator's standards do not.

[5] "The problem, as we see it, is how close you are going to identify it. I can't say the proposals of the industry made will make it possible to identify such products if they are all included in one standard of identity."

[6] Respondent agrees. It adds 100% of the minimum daily requirements of Vitamin D.

The testimony of two "industry representatives" was also cited (Adm. Br. 23). One of them thought there should be *minimum levels* to eliminate the danger of numerous flours with numerous values (R. 147). The other expressed no fear of confusion by the addition of different kinds of vitamins. He merely pointed out that there was difficulty in telling the people how much of a vitamin they were getting in a product (R. 311).

Then the Administrator cites the testimony of two "federal food and drug experts" (Adm. Br. 23). One of them[7] opposed a standard for a multiplicity of kinds of supplemented flours on the ground of confusion (R. 177).[8] As in the case of Miss Ross, Miss Chatfield's fear of confusion was based upon grouping differently fortified or enriched flours *under one name*, as shown by her testimony quoted in footnote 8. The other federal food and drug expert, Doctor Nelson, Chief of the Vitamin Division of the Food and Drug Administration, was in favor of a separate standard for flour *containing one or more optional ingre-*

[7] Charlotte Chatfield of the Bureau of Home Economics.

[8] The basis of Miss Chatfield's prognostication of confusion is shown by her later testimony on cross examination. She testified (R. 178):

> "Q. Miss Chatfield, do you think if a flour is fortified in some respects, in one or more respects, and is fortified or below the restoration point in other respects, it could be called a fortified flour and that be descriptive?
>
> A. I think that that would not be in line with the suggestion I was trying to make. It would make too many kinds of flours *that could be called by a single name, for example, "fortified flour."* • • • One manufacturer supplies one mineral and another one supplies another; and certain others supply one or another vitamin. *And if each of those is called "fortified flour," it would be extremely confusing.*"

Obviously if a host of different products were all designated in the same way, as "fortified farina" or "enriched farina," there would be confusion. But respondent does not call its product "enriched farina" and has no intention of so doing. Its product is called "Quaker Farina Wheat Cereal enriched with Vitamin D."

dients (R. 183, 193).[9] He did not propose a standard containing *required* ingredients as *a condition to the addition of the optional ones.*

The Administrator lifted from their contexts the portions of the testimony he quoted: It is important that consideration be given to what these witnesses were talking about. First, they were speaking of flour, not of farina. There had recently been placed on the market a great number of flours enriched with one or more elements (Finding 36, R. 617-18). These flours were being described by a variety of names. It was to the matter of avoiding confusion *between names* and of informing the purchaser as to what vitamins she was being given, that these witnesses were primarily addressing themselves. Farina was not in their minds. The record reveals only two farinas with added vitamins (Report of Presiding Officer, R. 562).[10] Farina did not receive the consideration to which it was entitled.[11] It was forced into the flour

[9] "Q. If we have a standard for enriched flour, in order to comply with the standard for enriched flour, would it have to contain all these vitamins you have indicated, or would it be an enriched flour if it contained any one or more of the optional ingredients? I am not clear as to just what your idea is.

"A. *It would be such a flour with one or more of the optional ingredients*" (R. 193).

[10] The Administrator says there were six or seven (Adm. Br. 23). This is incorrect.

[11] Finding 2: "Flour is used primarily for making white bread and biscuit, and consumers of flour normally expect that it will be suitable for these purposes" (R. 610-1). Finding 81: "Farina is used as a breakfast food and as an ingredient of macaroni products. • • • it is extensively used as a cereal food for children and in many cases is the only cereal food used during a period of their growth." (R. 626).

standards without consideration of its differences from flour.

Further, the testimony of these witnesses *as to flour* does not rise to the dignity of evidence even on this question of confusion *as to names*. It consists only of predictions as to what the witnesses *feared might* occur *if* enrichment *were accompanied by abuses*. No abuses were shown. No foundations of fact were laid for these *conditional* predictions.[12] No consumer tests were taken; no proof of actual cases of confusion was made. Moreover, the predictions were only the statements of opinion by persons who made no claim of being expert upon the question. Some of the witnesses were eminently qualified in their fields as scientists, but none of them was qualified as a prophet.[13]

Accordingly the Circuit Court of Appeals was correct in holding (R. 686):

> "The findings and argument predicated upon the possibilities for confusion of consumers, in optional partial enrichment, carry little, if any, weight. There was no evidence in support of such possibilities and they are entirely speculative and conjectural."

[12] The opinion of an expert witness must be based on facts in evidence (32 C. J. S. 219).

[13] The Administrator says that respondent did not object to this testimony (Adm. Br. 27n). But he knows that the testimony was taken with respect to flour with which respondent was not particularly interested and that, accordingly, respondent was not present by counsel. He also knows that in these hearings qualification has not been generally considered as going to admissibility but rather as bearing on weight. The Administrator also says that respondent did not except to the findings on confusion (Adm. Br. 27n). In this he is mistaken (Exception I. R. 598. By typographical error, Finding 83 is there quoted as embracing 33 to 34 instead of 34 to 43). Moreover, Section 701 of the Act does not make exception a prerequisite to judicial review.

At a previous point in its opinion, the Court below said (R. 684):

> "The conclusion that the regulations will promote honesty and fair dealing comes closer, in our judgment, to being one of law than of fact. If so, we are not bound to accept it. On the other hand, if it be considered as a finding of fact, we are of the view that it is *without substantial support.*"

Fortification of foods is not new. Respondent has been adding Vitamin D to farina for ten years (R. 218). If there were any basis for the Administrator's findings, he could undoubtedly have proved the confusion and misleading of consumers upon the basis of respondent's practices. Furthermore, if any of respondent's competitors had faced dishonest competition during the past ten years, evidence thereof could readily have been produced. The record is entirely devoid of any evidence of the confusion and misleading of consumers or of dishonest competition. What the record does show is that, instead of the multitude of different kinds of farina which the Administrator purports to fear, only one other farina with vitamins has appeared (R. 562).

It has been pointed out by the Circuit Court of Appeals that the situation is similar to that in *Federal Trade Commission v. Raladam Company*, 283 U. S. 643, where this Court said (pp. 652-3):

> "• • • there is neither finding nor evidence from which the conclusion legitimately can be drawn that these advertisements substantially injured or tended thus to injure the business of any competitor or of competitors generally, whether legitimate or not. None of the supposed competitors appeared or was called upon to show what, if any, effect the misleading advertisements had, or were likely to have, upon his business. • • • It is impossible to say whether, as a result of Respondent's advertisements, any business was diverted, or was likely to be diverted, from others

engaged in like trade, or whether competitors, identified or unidentified, were injured in their business, or were likely to be injured, or, indeed, whether any other anti-obesity remedies were sold or offered for sale in competition, or were of such a character as naturally to come into any real competition with Respondent's preparation in the interstate market. *All this was left without proof and remains, at best, a matter of conjecture. Something more substantial than that is required as a basis for the exercise of the authority of the Commission.*"

The Administrator seeks to justify the substitution of guesswork and speculation for evidence upon the authority of *Electro Thermal Co.* v. *Federal Trade Commission*, 91 F. (2d) 477, 480. In that case, however, the abuses were *proved* and the court merely presumed the resultant injury from such *proved* abuses. The Administrator also cites *Federal Trade Commission* v. *Raladam Co.*, 316 U. S. 149, 151-152.[14] But in that case, too, the fact of deception was *proved* and this Court presumed the injury upon the basis of *proved* deception.[15] Upon the basis of these cases[16] the

[14] Another controversy between the same parties as were involved in *Federal Trade Commission* v. *Raladam Co.*, 283 U. S. 643, which is discussed above.

[15] This Court pointed out that in the prior *Raladam* case there was neither finding nor evidence from which the conclusion could be drawn and then went on to say: "This time the Commission found with meticulous particularity that Raladam had made many misleading and deceptive statements to further sales of Marmola; * * *"

[16] The Administrator also cites the trade-mark cases of *McLean* v. *Fleming*, 96 U. S. 245, 251, *United Drug Company* v. *Obear-Nester Glass Company*, 111 F. (2d) 997, 999-1000, and *Charles Broadway Rouss, Inc.* v. *Winchester Co.*, 300 F. 706, 723-724 (Adm. Br. 29n). But in these cases, too, the facts of the similarity between the parties' marks were *proved* and the presumption that confusion would be likely to result was based upon these *proved* facts. Compare *Kellogg Company* v. *National Biscuit Company*, 305 U. S. 111, 122, where this Court refused to indulge the presumption because the fact had not been proved. This Court said, "There is no evidence of passing off or deception on the part of the Kellogg Company; and it has taken every reasonable precaution to prevent confusion or the practice of deception in the sale of its product."

Administrator now asks this court, first to *presume* that abuses will occur and then to *presume* resultant injury from the *presumed* abuses. In the cited cases X was proved, and from X the court presumed Y. Now the Administrator claims the right to presume both X and Y where nothing has been proved. Of course, the Administrator must make a judgment *in futuro*. We only ask him to make his judgment *in futuro* on the basis of *proved facts*.

Predictions are not difficult to make, nor to obtain, if the prophet is not required to base his divinations upon facts or show that he is qualified to make his prophecies. If the obtaining of such predictions is the only requirement for the assertion of administrative control and is permitted to stand even though disputed by proved facts, it is difficult to imagine any situations over which such control cannot be exercised. Such a holding would emasculate the requirement that standards be based upon substantial evidence. The following admonition of the court in *National Labor Relations Board* v. *Sheboygan Chair Co.* (C. C. A. 7th), 125 F. (2d) 436, 439 is pertinent here:

> "The Board should not discard the positive credible testimony of witnesses in favor of an inference drawn from tenuous circumstances that at best could have supported only *an anemic suspicion*. Such an inference does not meet the test of substantial evidence."

In *Consolidated Edison Company* v. *National Labor Relations Board*, 305 U. S. 197, 230, this Court used these words:

> "* * * this assurance of a desirable flexibility in administrative procedure does not go so far as to justify orders without a basis in evidence having rational probative force. Mere uncorroborated hearsay or rumor does not constitute substantial evidence."

So also in *Appalachian Electric Power Company* v. *National Labor Relations Board*, 93 F. (2d) 985, 989, the court said:

> "• • • substantial evidence is evidence furnishing a substantial basis of fact from which the fact in issue can reasonably be inferred; and the test is not satisfied by evidence which merely creates a suspicion or which amounts to no more than a scintilla or which gives equal support to inconsistent inferences."

C.

Respondent's Contention that Vitamin D Should Be Included as an Optional Ingredient in the Farina Standard Is Supported by Substantial Evidence.

It has been pointed out that substantial evidence does not support the Administrator's treatment of Vitamin D whereby it was excluded from the farina standard and relegated to another standard for a hitherto unknown product which was given the name of "enriched farina." Not only was there not substantial evidence to support this treatment, there was in fact substantial evidence in opposition to it.

In addition to the proof of the long established usage by respondent of Vitamin D in its product (R. 218), the record shows that a deficiency of Vitamin D exists in large numbers of infants and children (R. 84);[17] that Vitamin D is valuable as an added nutrient in farina in the prevention and therapy of rickets and in the building of strong bones and teeth (R. 78), particularly in infants and children who make up a large class of farina consumers;[18] and that re-

[17] It has been pointed out that this widespread deficiency of Vitamin D in infants and children is specifically found by Administrator's Finding 35 (R. 617).

[18] Administrator's Finding 81 (R. 626).

spondent's product has received excellent consumer acceptance (R. 218). Respondent also adduced a mass of expert testimony to the effect that Vitamin D should be permitted as an optional ingredient in farina (R. 86, 217-8, 422-3, 433, 555-6).

It is to be noted that all of the evidence respecting vitamin and mineral additions to *farina* was on the basis of such addition as optional ingredients.[19] Indeed, there is nowhere in the record a scintilla of evidence concerning the non-existent product "enriched farina." The testimony introduced by the Administrator himself related not to "enriched farina," but only to farina.[20] Evidence offered by others also related only to farina alone and to farina with optional ingredients (R. 216-225, 266-322, 421-434, 555-556). The first notice to respondent that the hearing had given birth to a new product was the issuance of the Proposed Orders and Findings (R. 567).[21]

It is submitted that the above discussion demonstrates that the Administrator ignored the testimony adduced by the respondent and substituted therefor inadmissible predictions of his own witnesses, thereby nullifying the statutory requirement for substantial evidence.

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[19] Testimony of Doctor Scott (R. 76-93, 421-434), Doctor Gunderson (R. 216-225), and Doctor Harris (R. 266-322).

[20] Testimony of Joseph Calloway, Jr. (R. 205-213) and Dr. Virell E. Munsey (R. 213-216).

[21] The hearing had been entitled as follows: "In the Matter of a Definition and Standard of Identity for each of the following foods: • • • (I) Farina; and (J) Semolina" (R. 12). In the Proposed Order and Findings the caption had been changed to read: "In the Matter of a Definition and Standard of Identity for each of the Following Foods: • • • (M) Farina; (N) Enriched Farina; (O) Semolina" (R. 567).

III.

THE FARINA AND ENRICHED FARINA STANDARDS DO NOT ACCOMPLISH THE PURPOSES OF THE ACT.

A.

The Purposes of the Act Are to Secure the Purity of Foods and to Inform Purchasers of What They Are Buying.

Although from time to time the Administrator seems to argue that his regulatory powers are the same as those of Congress (*supra* pp. 33-4), it is beyond sound dispute that his powers are delegated and consist only of those plainly explicit in or reasonably to be inferred from the Act granting him the powers. To determine his powers, we must first know the purposes of the Act. In part, Section 401 of the Federal Food, Drug and Cosmetic Act of 1938 (21 U. S. C. A. 341) reads:

> "Whenever in the judgment of the Administrator *such action will promote honesty and fair dealing in the interest of consumers*, he shall promulgate regulations fixing and establishing for any food, under its common or usual name so far as practicable, *a reasonable definition and standard of identity*, a reasonable standard of quality, and/or reasonable standards of fill of container: * * *"

In support of the farina standard and the enriched farina standard which the Administrator promulgated in furtherance of his dietary "food standards program" or "enrichment program,"[1] he argues that there is a tendency toward consumer confusion and that if the standards he has promulgated for farina and enriched farina minimize such confusion in enriched foods, public health will be benefited and honesty and fair dealing thus promoted.

[1] So called in the Administrator's Petition for the Writ of Certiori, pages 12 and 15.

Section 10, as amended, of the Food and Drug Act of 1906 (21 U. S. C. 10) contained a provision empowering the Secretary of Agriculture to promote certain standards for canned foods. That Section used language identical in its pertinent parts to the language in Section 401. It empowered the Secretary of Agriculture to promulgate reasonable standards of quality, etc., for certain canned foods there covered and he was limited in his power to promulgate such standards to those that would in his judgment "promote honesty and fair dealing in the interest of consumers." This Section was construed in *Nolan* v. *Morgan*, 69 F. (2d) 471, (C. C. A. 7). The court interpreted the words in the statute "promote honesty and fair dealing in the interest of consumers" as meaning what this Court in *U. S.* v. *Antikamnia Chemical Company*, 231 U. S. 654, 665, said the Food and Drug Act of 1906 as a whole meant, that is:

> "The purpose of the Act is to secure the purity of food and drugs, and to inform purchasers of what they are buying."

And again interpreting the words "promote honesty and fair dealing in the interest of consumers" the Seventh Circuit Court of Appeals in the present case said (R. 684-5):

> "That the promotion of honesty and fair dealing was intended by Congress to mean something other than the promotion of the consumers' health is plainly ascertainable from a study of the Act. Likewise, it is clear that action was not authorized merely to avoid confusion on the part of consumers, nor to educate the public as to dietary requirements. If Congress had so intended, it would, no doubt, have employed the appropriate language. While there may be some relevancy between the promotion of health and that of honesty and fair dealing, they certainly are not synonymous terms. Injury to health does not necessarily follow from dishonesty and unfair dealing in food products.

and neither does health improvement necessarily follow from honesty and fair dealing."

B.

The Farina and Enriched Farina Standards Do Not Secure the Purity of Foods Nor Do They Inform Purchasers of What They Are Buying.

Under the Federal Food, Drug and Cosmetic Act there are only two things which are actionable either by seizure and condemnation or by criminal proceedings. One is in case the food be *adulterated* and the other is if it be *misbranded*. Since the Administrator urges that standards of identity "might condemn wholesome nonconforming foods without benefit of reprieve by label disclosure" (Adm. Br. 43-4), he does not invoke Section 402 relating to adulterated foods. He admits that farina with Vitamin D added is a wholesome product and that there is no question of the use in or addition to that product of any harmful or deleterious substance. Consequently the Administrator's exclusion of Vitamin D as an optional ingredient in farina does not aid in securing the purity of foods. The standard, then, must be defended upon the basis of educating or informing the public. On the subject of informing consumers the Court below had this to say (R. 686-7):

> "Furthermore, we should think that a product manufactured in accordance with the regulations in suit *would tend to increase rather than retard confusion. This is especially true as to enriched farina.* No such product has been sold heretofore under that designation. The manufacturer will be required only to label it 'enriched farina' unless the option to add Vitamin D is exercised, in which case such addition must be stated. *How the ordinary consumer will be informed so as to avoid confusion as to what is meant by enriched farina, its contents, or the benefits to be expected from its use,*

> *is a mystery which we are not able to fathom.* How the contention that confusion is likely to result from a product, such as petitioner's, *which truthfully informs the consumer as to what he is buying*, can be reconciled with the contention that a product sold as enriched farina, without any further description, will lessen or avoid confusion, is beyond our comprehension."

The Administrator's argument that his standards will tend to lessen confusion all seems to hinge upon his fear, unsupported by evidence, of possible *advertising* abuses (Adm. Br. 24, 26-27). It has heretofore been shown that this so-called evidence does not constitute any basis for the Administrator's findings respecting confusion (*supra* pp. 40-46). However, the Federal Trade Commission under the Wheeler-Lea Amendment has jurisdiction over false and misleading advertising of foods, drugs and cosmetics.[2] It has the power and the duty to prohibit, enjoin and punish false or misleading advertising. As a matter of fact, the Vitamin B complex restoration program of the Administrator suggests "a tremendous advertising campaign" (R. 116) in which in every possible manner **Whole Wheat Values** or **Restored to Whole Wheat Values** would be stressed either without qualification, or with the obscure statement "restored to whole wheat values of Vitamin B_1, nicotinic acid and iron." No reference would be made to the absence of bran or reduction in amount of germ or any other change

[2] Federal Trade Commission Act, as amended, 15 U. S. C. A. 41. The House Committee in its report on the final draft of the Wheeler-Lea Amendment to the Federal Trade Commission Act filed August 19, 1937, as House Report 1613, 75th Congress, First Session, said:

> "The common motive of false advertisement is the same in every line of industry, to gain an economic advantage through defrauding or misleading the purchaser. This method of protecting the public should be harmonized and unified under one organization with consistent and uniform methods of enforcement and penalization."

in or damage to the nutritive values of the product caused by the processing, nor to the fact that the restored values are insignificant (*infra* p. 59).

Since respondent began marketing its product in April, 1932, the label has clearly and without ambiguity informed purchasers of what they are buying. It has described the product as "Quaker Farina Wheat Cereal enriched with Vitamin D." No expert testimony is needed to demonstrate that this description of the product is honest and is clearer, more specific, and less likely to confuse anyone than the mere description of the product as "enriched," which does not inform the purchaser in what respect the enrichment has been accomplished. The inferences which may be drawn from the blanket description "enriched" are unlimited. It could mean that powdered milk had been added. It could mean that the protein content had been stepped up. It could mean that the product was richer in fats or carbohydrates. Certainly such a standard does not inform consumers of what they are buying.

Moreover, the record shows that respondent's enrichment is no *partial* enrichment with Vitamin D. Respondent's product contains in a single serving *100 per cent* of the consumer's minimum daily requirements for this vitamin (R. 218). Contrast this with the Administrator's enriched farina standard which provides for the addition of varying quantities of Vitamin B_1, riboflavin, nicotinic acid and iron (*infra* p. 59), none of them to the extent of the consumer's total minimum daily requirements. In determining the amount of vitamins to be added, the Administrator has ignored the mass of testimony bearing upon the consumers' requirements and has based his enrichment standard upon the insignificant and utterly irrelevant requirement of the wheat berry (Adm. Br. 55). The Administrator's condemnation of "partial enrichment," therefore, would be more properly directed at his enriched farina

standard than at respondent's product. It is clear from the testimony of Dr. Elmer M. Nelson, Chief of the Vitamin Division of the Food and Drug Administration (*infra* pp. 57-9, R. 182) that the "indiscriminate enrichment" to which he took exception is not the substantial addition of any one vitamin or mineral, but the nutritively insignificant addition of *any one or more vitamins or minerals.*

C.

The Farina and Enriched Farina Standards Promote Dishonesty and Unfair Dealing.

The food, farina, has long been known and used. The food, enriched farina, was nonexistent until created by the Administrator. The record is clear (*supra* pp. 49-50) that the addition of Vitamin D to farina *improves* the product by making available to infants and children Vitamin D needed by them to combat the deficiency of Vitamin D which the Administrator has found exists in "large numbers of infants and children" (Finding 35, R. 617). Nevertheless, the Administrator would make it a criminal offense (Section 303 of the Federal Food, Drug and Cosmetic Act of 1938, 21 U. S. C. A. 333) for respondent to continue marketing its improved product "Quaker Farina Wheat Cereal enriched with Vitamin D." He would deprive consumers of an established, beneficial product which is admittedly superior nutritively to farina without Vitamin D added. He would deprive infants and children, who are the largest consumers of farina (R. 217, 272, 626), of Vitamin D which the Administrator has found they greatly need. And he says he would do this to promote honesty and fair dealing in the interest of consumers.

If there is any evidence in support of the Administrator's enriched farina standard it is evidence supporting a stand-

ard of "quality"[3] and not of "identity."[4] It requires no argument to demonstrate that farina is farina, whether or not additional vitamins have been added. The identity of the product is still the same. The quality of the product may be changed. If the enriched farina standard is a standard of quality and not a standard of identity, the farina standard of identity must, in the eyes of the Administrator himself, be wholly unreasonable because it does not contain provision even for the addition of the Vitamin B complex. But whether the enriched farina standard is a standard of quality (and thus void because no notice was given or public hearing held for a standard of quality as required by the Act) or a standard of identity, it constitutes a fraud upon the public. That this is so appears in part from the testimony of Dr. Elmer M. Nelson, Chief of the Vitamin Division of the Food and Drug Administration, the Administrator's main spokesman on vitamins at the hearings. He testified (R. 181-3):

> "Honesty and fair dealing in the interest of the consumer would not be promoted by including vitamins and minerals as optional ingredients of flour unless minimum standards are specified for each of the vitamins or minerals that may be used as optional ingredients.
>
> . . . . . .
>
> "Testimony has been offered at this hearing that the purpose of adding these optional ingredients which

[3] Webster's New International Dictionary, Second Edition, defines *quality* as: "1. That which constitutes (something); proper or essential being; character; nature; kind; 2. hence, an attribute; a characteristic; 3. Distinctive or peculiar character; distinctive trait, power, capacity, or virtue;"

[4] Webster defines *identity* as: "1. a Sameness of essential or generic character in different examples or instances; the limit approached by increasing similarity; as, the identity of the red in the rug with the red of a brick. b Sameness in all that constitutes the objective reality of a thing; . . ."

are intended to improve the nutrient value of bread is to benefit the public health. *Now, if flour which is fortified with vitamins or minerals is to serve that purpose, it becomes important that a substantial quantity of the vitamins or minerals should be added. I do not believe that the desired objective can be reached by restoration of flour as described by Dr. Wilder.*

"If we consider only the addition of calcium to white flour to the extent to make it equal in calcium content to whole wheat flour, we would then have roughly 10 per cent or less of the minimum daily requirement of calcium, and that is not accomplishing the purpose for which these vitamins and minerals should be added. *There should be some very definite improvement of the diet if such additions are to be of advantage to the consumer.*

"*Neither do I subscribe to the view expressed by Dr. Wilder that vitamins should be added to a type of food in which you expect to find that vitamin.* If people were actually guided in the manner that he suggested, they would choose whole wheat bread if their diet was insufficient in Vitamin B_1, rather than white bread, and we would have no necessity for fortification of white flour as has been here expressed.

"*I think there are other more important considerations in guiding us as to what vitamins should be added to flour.* Of prime importance is the question of whether flour is a suitable carrier so that the vitamin will not deteriorate, either in the flour itself or after it has been subjected to any cooking or baking process.

"Also of prime importance is whether the food which has been fortified with the vitamin and mineral actually reaches the group of people who should be benefited. *It has been testified here that dietary deficiencies are more likely to occur in low-income groups, and I concur in that opinion.* Therefore, the foods which will reach those groups should be fortified, if any foods are to be fortified with vitamins or minerals.

"If the addition of vitamins and minerals is to serve a useful purpose, it seems to me that if any vitamin is added to flour it should provide about one-fourth of the minimum daily requirement of that vitamin, and the same is true of minerals."

The following table clearly demonstrates that the Administrator's enriched farina standard obviously contravenes the principle of "definite improvement of the diet" in terms of minimum daily requirements as stated by Dr. Nelson:

Nutritional Substance	One serving enriched farina* Percentage of minimum daily requirement provided† Adult	Child	Infant
Required			
Vitamin B_1	10.37%	13.83% (6 to 12 yrs.) 20.74% (1 to 6 yrs.)	41.48%
Riboflavin	3.75%	Minimum Daily Requirement not declared	15.00%
Nicotinic Acid	Minimum Daily Requirement not declared		
Iron	3.75% (and for child 6 or more years)	5.00% (for child 1 to 6 yrs.)	Minimum Daily Requirement not declared
Optional			
Vitamin D	3.90%‡	3.90%	3.90%
Calcium	4.17%	4.17%	Minimum Daily Requirement not declared

*One ounce constitutes a serving (R. 86, 219).

†Based upon minimum daily requirements as provided in special dietary regulations, under Section 403 (j), (6 Fed. Reg. 5921-5926, issue of November 22, 1941). For quantities from which above percentages were determined, see Final Order (R. 637-8).

‡As contrasted with 3.90% provided by the enriched farina standard, respondent adds 100% of the minimum daily requirement of Vitamin D to one serving of its product (R. 218).

Thus the riboflavin, calcium, iron and Vitamin D provided for infants, children and adults, and the Vitamin B_1 provided for children and adults furnished by the Administrator's enriched farina standard are *insignificant* according to the testimony of Dr. Nelson, the Administrator's chief vitamin expert. Only in the case of the minimum daily infant requirements for Vitamin B_1 does the Administrator's enriched farina standard meet Dr. Nelson's principle of "definite improvement of the diet," that is, "approximately one-fourth of the minimum daily requirements."

The explanation of why the Administrator specified such *low* minimum amounts of the added ingredients (both required and optional) in "enriched farina" is apparent. He first established minimum quantities of these ingredients *per pound of enriched flour* (R. 629-30). He then provided *the identical amounts per pound for enriched farina.* His mistake was in ignoring—or simply completely *forgetting* —that the average daily serving of *flour* is *6½ ounces*, whereas the average daily serving of *farina* is *one ounce* (R. 47, 119, 183, 219). The result, of course, is that the average consumer of enriched *flour* will receive *six and one-half times* the amount of each of its vitamin and mineral additions as will the average consumer of enriched *farina.*

Unquestionably, Dr. Nelson, as Chief of the Vitamin Division of the Food and Drug Administration, has condemned such a product as the Administrator's "enriched farina" as "not accomplishing the purpose for which these vitamins and minerals should be added." And Dr. Wilder, upon whose testimony the Administrator obviously relies so much, agrees.[5] Nevertheless, the Administrator insists

[5]See his testimony, commencing R. 361, respecting minimum additions for 6½ ounces of *flour*, then considered the average daily consumption.

that if manufacturers meet this nutritionally insignificant standard they must, without qualification, label the product "enriched." The consumer is not told how the product is enriched, with what it is enriched, or how little it is enriched. The Administrator encourages unscrupulous manufacturers to mislead and defraud the consumer into believing he is getting a product of greatly superior nutritive value when in fact the improvement in the product is almost nonexistent.

Vitamin substances are expensive (R. 137). The above table shows that the addition of Vitamin B_1, riboflavin, nicotinic acid and iron as required ingredients before Vitamin D can be added will result in increasing the cost of farina to consumers without significant nutritional benefit. Instead of enriching its farina with insignificant quantities of a number of vitamins and minerals, respondent adds 100 per cent of the minimum daily requirements of Vitamin D to its farina, as contrasted with 3.90 per cent of the minimum daily requirements prescribed in the enriched farina standard. The Administrator's enriched farina standard obviously fosters "indiscriminate enrichment" of the worst kind. It does not "promote honesty and fair dealing." It does not "secure the purity of food and drugs, and inform purchasers of what they are buying." *U. S.* v. *Antikamnia Chemical Company*, 231 U. S. 654, 665.

Of course, the Administrator fixed the enriched farina standard with no intent to promote fraud. Obviously he fixed the standard for flour, and then extended it to farina without consideration of the different uses and functions of the two products. But that makes the standard no more reasonable. It is still illegal.

Clearly, the purpose of the Act will be served and consumers will be benefited by the inclusion of Vitamin D as

an optional ingredient in farina. There is no objection to naming it on the label, as respondent has always done.

IV.

THE ADMINISTRATOR CITES NO AUTHORITY JUSTIFYING HIS ORDER PREVENTING THE SALE OF FARINA IMPROVED BY THE ADDITION OF VITAMIN D.

That the present case is unlike any food or drug case which previously has come before the courts is perhaps best shown by the many authorities relied upon by the Administrator in his brief, particularly in the historical section dealing with the background and purposes of Section 401 of the Act (Adm. Br. 30-45). This is not a case in which an inferior product is being "palmed off on the public" or sold as "in imitation of" a superior product (Adm. Br. 38-40); the *Bred Spred* cases, *U. S.* v. *Fifteen cases of Bred Spred*, 35 Fed. (2d) 183; *U. S.* v. *Ten Cases More or Less Bred Spred*, 49 Fed. (2d) 87 and others, involving a product containing half the normal fruit content of jam being palmed off as and sold in imitation of jam). This is not a case involving the dilution of a product by increasing the content of a cheaper, inferior ingredient in the product and thereby lowering the content of the better, more expensive ingredient (Adm. Br. 47, 58; *Houston* v. *St. Louis Independent Packing Co.*, 249 U. S. 479, involving a product sold as sausage but containing more cereal, the cheap ingredient, and less meat, the expensive ingredient, than the product commonly known as "sausage"). This is not a case of selling an adulterated product which, as the Court below said, is "injurious to health and a fraud upon the public" (R. 688; Adm. Br. 57; *U. S.* v. *Carolene Products Co.*, 304 U. S. 144, involving the sale of skimmed milk compounded with fat or oil other than milk fat so as to *resemble* milk or cream; *Hebe* v. *Shaw*, 248 U. S. 297). This

is not a case of false labeling involving misrepresentation as to the source of origin of a product (Adm. Br. 47; *Huesner & Son* v. *Federal Trade Commission*, 106 Fed. (2d) 596, involving the use of the word "Havana" on cigars not made in Cuba). This is not a case of the addition of *poisonous* or *deleterious* substances to a product (Adm. Br. 37; Sections 402 (a), (1) and (2) of the Act). This is not a case of the substitution in a food of substances "which make the food appear *better* or of *greater value* than it is" (Adm. Br. 37). This is not a case in which "the public" has been "*victimized*" (Adm. Br. 43 n. 32; the Butter Standard Act, 21 U. S. C. A. 321a). This is not a case involving a food which is *substandard* in quality (Adm. Br. 12, 35). This is a case involving a product, farina with Vitamin D, which is *superstandard* in quality.

The Administrator's reliance throughout his brief on cases and fact situations such as outlined above and his inability to cite any case whatsoever even remotely resembling the case at bar, demonstrates quite conclusively, we think, that he has gone far afield in entering the order here under attack. The conclusion is inevitable that the Administrator in entering the order under review far exceeded his statutory authority, acted unreasonably, arbitrarily, capriciously and without substantial evidence.

CONCLUSION.

The right of parents to rear their children in health is fundamental. So is the right of a child to possess a body of sound skeletal structure. So is the right of one to make and honestly sell good food for human consumption. None of these rights should be limited beyond the minimum extent necessary in the public interest.

Congress did not, in Section 401 of the Food, Drug and Cosmetic Act of 1938, lodge power in the Administrator

to establish diets or create new foods. The Congressional grant does not go beyond that of promoting honesty and fair dealing in the interest of consumers by regulations promulgating for foods under their common names, as far as practicable, reasonable definitions and standards of identity, reasonable standards of quality and reasonable standards of fill of container. Farina with Vitamin D added has long been an established food. It is extensively used as a cereal food for children. Respondent's product contains enough Vitamin D to prevent the disease rickets. That it is a good food is not questioned. Its package label plainly identifies it. Its quality is unchallenged. Its quantity is truthfully represented.

The need for Vitamin D is great. This is particularly true among children. Farina is a good carrier. As such it has a ten year history. It is now a well-known product. That the consumers wish this food is proved by its wide use. That it is beneficial is not denied. It is wholly unreasonable to bar it. There is no need to bar it. So to do is contrary to the public interest. There is no substantial evidence warranting its death on the market. The evidence that it should endure is strong.

Under the excuse of preventing confusion, the Administrator offers manufacturers and the public a new food. It has never been made or sold. It is called "enriched farina." It will be more expensive to make. If produced, it is likely that it must be sold at a higher price. If made, the parents of children who can afford it may buy it. Those who cannot afford to buy it also will be economically unable to patronize the drugstore or the milkman. For them the only hope is exposure to sunshine. In the large centers and in most seasons of the year this is a false hope.

There is no confusion respecting the established food farina with Vitamin D added. There has been no confusion

for ten years. This does not warrant the postulate that there will be confusion in the future. "Enriched farina," if made and sold, will promote confusion. The manufacturer of "enriched farina", if one appears, needs only to label the product "enriched farina", unless Vitamin D is added or calcium is added, or wheat germ is added, or disodium phosphate is added. In each of these cases the additions must be stated. The phrase "enriched farina" is to mean that in the farina product is contained not less than 1.66 milligrams of Vitamin B_1, not less than 1.2 milligrams of riboflavin, not less than 6 milligrams of nicotinic acid or nicotinic acid amide, and not less than 6 milligrams of iron. This means that enriched farina will supply 20.74% of the minimum daily requirements of Vitamin B_1 for the child from one to six years of age and 5% of his minimum daily requirement of iron. In respect to optional ingredients, it may contain 3.90% of that child's minimum daily requirement of Vitamin D and 4.17% of his minimum daily requirement of calcium. As to infants, that is those a year old or less, some of these percentages are somewhat higher, but as to adults they are considerably lower. Since this is the import and the meaning of "enriched farina", the honest seller must either add to his label the explanation that the quantities of most of the added ingredients are insufficient to be of any value; or should make the quantities sufficient to be of value and meet somehow the competition of those who will be contented with the inadequate requirements of the Administrator's definition of "enriched farina".

The order of the Administrator is wholly unreasonable. It is not promotive of honesty and fair dealing. It is not in the interest of the consumer. It is unreasonable in respect to identity. It is unreasonable in respect to quality. The established food, farina with Vitamin D added, is in

wide use. The consumers have a right to use it. There is no confusion about it. The only confusion respecting farina is that which has been imported into the matter by the Administrator's order.

Respectfully submitted,

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SUPREME COURT OF THE UNITED STATES.

No. 424.—October Term, 1942.

Federal Security Administrator, Petitioner, *vs.* The Quaker Oats Company.	On Writ of Certiorari to the United States Circuit Court of Appeals for the Seventh Circuit.

[March 1, 1943.]

Mr. Chief Justice Stone delivered the opinion of the Court.

The Federal Security Administrator, acting under §§ 401 and 701(e), of the Federal Food, Drug and Cosmetic Act, 52 Stat. 1040, 1046, 1055, (21 U. S. C. §§ 341, 371), promulgated regulations establishing "standards of identity" for various milled wheat products, excluding vitamin D from the defined standard of "farina" and permitting it only in "enriched farina", which was required to contain vitamin B_1, riboflavin, nicotinic acid and iron. The question is whether the regulations are valid as applied to respondent. The answer turns upon (a) whether there is substantial evidence in support of the Administrator's finding that indiscriminate enrichment of farina with vitamin and mineral contents would tend to confuse and mislead consumers; (b) if so, whether, upon such a finding, the Administrator has statutory authority to adopt a standard of identity, which excludes a disclosed non-deleterious ingredient, in order to promote honesty and fair dealing in the interest of consumers; and (c) whether the Administrator's treatment, by the challenged regulations, of the use of vitamin D as an ingredient of a product sold as "farina" is within his statutory authority to prescribe "a reasonable definition and standard of identity."

Section 401 of the Act provides that "Whenever in the judgment of the Administrator such action will promote honesty and fair dealing in the interest of consumers, he shall promulgate regulations fixing and establishing for any food, under its common or usual name so far as practicable, a reasonable definition and standard of identity . . . . In prescribing a definition and standard of identity for any food or class of food in which optional ingredients are permitted, the Administrator shall, for the purpose

of promoting honesty and fair dealing in the interest of consumers," designate the optional ingredients which shall be named on the label." By § 701(e) the Administrator, on his own initiative or upon application of any interested industry or a substantial part of it, is required to "hold a public hearing upon a proposal to issue, amend or repeal any regulation contemplated by" § 401. At the hearing "any interested person may be heard". The Administrator is required to promulgate by order any regulation he may issue, to "base his order only on substantial evidence of record at the hearing", and to "set forth as part of his order detailed findings of fact on which the order is based."[1]

Any food which "purports to be or is represented as a food for which a definition and standard of identity has been prescribed" pursuant to § 401 is declared by § 403(g) to be misbranded "unless (1) it conforms to such definition and standard, and (2) its label bears the name of the food specified in the definition and standard, and, insofar as may be required by such regulations, the common names of optional ingredients . . . present in such food". The shipment in interstate commerce of "misbranded" food is made a penal offense by §§ 301 and 303. "In a case of actual controversy as to the validity" of an order issuing regulations under § 401 any person "adversely affected" by it may secure its review on appeal to the Circuit Court of Appeals for the circuit of his residence or principal place of business. On such review the findings of the Administrator "as to the facts, if supported by substantial evidence, shall be conclusive." § 701(f)(1), (f)(3).

After due notice[2] and a hearing in which respondent participated, the Administrator by order promulgated regulations establishing definitions and standards of identity for sixteen milled wheat products, including "farina" and "enriched farina". Regulation 15.130 defined "farina" as a food prepared by grinding and bolting cleaned wheat, other than certain specified kinds, to a prescribed

[1] As enacted, the Act vested the foregoing powers in the Secretary of Agriculture. By §§ 12 and 13 of Reorganization Plan No. IV, 54 Stat. 1234, 1237, approved April 11, 1940, the Federal Food and Drug Administration and all functions of the Secretary of Agriculture relating thereto were transferred to the Federal Security Agency and the Federal Security Administrator.

[2] Respondent contended in the court below that the notice was inadequate. It appears to have abandoned that contention here, but in any event we think that it is without merit in view of respondent's participation in the original hearing, and in view of the publication of notice of a reconvened hearing devoted solely to the "propriety of the addition of vitamins and minerals to . . . (1) farina . . . ".

fineness with the bran coat and germ of the wheat berry removed to a prescribed extent. The regulation made no provision for the addition of any ingredients to "farina". Regulation 15.140 defined "enriched farina" as conforming to the regulation defining "farina", but with added prescribed minimum quantities of vitamin B_1, riboflavin,[3] nicotinic acid (or nicotinic acid amide) and iron. The regulation also provided that minimum quantities of vitamin D, calcium, wheat germ or disodium phosphate might be added as optional ingredients of "enriched farina", and required that ingredients so added be specified on the label. In support of the regulations the Administrator found that "unless a standard" for milled wheat products "is promulgated which limits the kinds and amounts of enrichment, the manufacturers' selection of the various nutritive elements and combinations of elements on the basis of economic and merchandising considerations is likely to lead to a great increase in the diversity, both qualitative and quantitative, in enriched flours offered to the public. Such diversity would tend to confuse and mislead consumers as to the relative value of the need for the several nutritional elements, and would impede rather than promote honesty and fair dealing in the interest of consumers."

On respondent's appeal from this order the Court of Appeals for the Seventh Circuit set it aside, 129 F. 2d 76, holding that the regulations did not conform to the statutory standards of reasonableness, that the Administrator's findings as to probable consumer confusion in the absence of the prescribed standards of identity were without support in the evidence and were "entirely speculative and conjectural", and that in any case such a finding would not justify the conclusion that the regulations would "promote honesty and fair dealing in the interest of consumers." We granted certiorari, 317 U. S. —, because of the importance of the questions involved to the administration of the Food, Drug and Cosmetic Act.

Respondent, The Quaker Oats Company, has for the past ten years manufactured and marketed a wheat product commonly used as a cereal food, consisting of farina as defined by the Administrator's regulation, but with vitamin D added. Respondent dis-

[3] The effective date of the riboflavin requirement has been postponed until April 20, 1943, because it appeared that the available supply was inadequate. 7 Fed. Reg. 3033.

tributes this product in packages labeled "Quaker Farina Wheat Cereal Enriched with Vitamin D", or "Quaker Farina Enriched by the Sunshine Vitamin". The packages also bear the label "Contents 400 U. S. P. units of Vitamin D per ounce, supplied by approximately the addition of 1/5 of 1 percent irradiated dry yeast".

Respondent asserts, and the Government agrees, that the Act as supplemented by the Administrator's standards will prevent the marketing of its product as "farina" since, by reason of the presence of vitamin D as an ingredient, it does not conform to the standard of identity prescribed for "farina", and that respondent cannot market its product as "enriched farina" unless it adds the prescribed minimum quantities of vitamin B_1, riboflavin, nicotinic acid and iron. Respondent challenges the validity of the regulations on the grounds sustained below and others so closely related to them as not to require separate consideration.

As appears from the evidence and the findings, the products of milled wheat are among the principal items of the American diet, particularly among low income groups.[4] Farina, which is a highly refined wheat product resembling flour but with larger particles, is used in macaroni, as a breakfast food, and extensively as a cereal food for children. It is in many cases the only cereal consumed by them during a period of their growth. Both farina and flour are manufactured by grinding the whole wheat and discarding its bran coat and germ. This process removes from the milled product that part of the wheat which is richest in vitamins and minerals, particularly vitamin B_1, riboflavin, nicotinic acid and iron, valuable food elements which are often lacking in the diet of low income groups. In their diet, especially in the case of children, there is also frequently a deficiency of calcium and vitamin D, which are elements not present in wheat in significant quantities. Vitamin D, whose chief dietary value is as an aid to the metabolism of calcium, is developed in the body by exposure to sunlight. It is derived principally from cod liver and other fish oils. Milk is the most satisfactory source of calcium in digestible form, and milk enriched by vitamin D is now on the market.

In recent years millers of wheat have placed on the market flours and farinas which have been enriched by the addition of various

[4] One witness at the hearing referred to estimates that over 95% of human consumption of wheat products is in the form of white flour.

vitamins and minerals. The composition of these enriched products varies widely.[5] There was testimony of weight before the Administrator, principally by expert nutritionists, that such products, because of the variety and combination of added ingredients, are widely variable in nutritional value; and that consumers generally lack knowledge of the relative value of such ingredients and combinations of them.

These witnesses also testified, as did representatives of consumer organizations which had made special studies of the problems of food standardization, that the number, variety and varying combinations of the added ingredients tend to confuse the large number of consumers who desire to purchase vitamin-enriched wheat food products but who lack the knowledge essential to discriminating purchase of them; that because of this lack of knowledge and discrimination they are subject to exploitation by the sale of foods described as "enriched" but of whose inferior or unsuitable quality they are not informed. Accordingly, a large number of witnesses recommended the adoption of definitions and standards for "enriched" wheat products which would ensure fairly complete satisfaction of dietary needs, and a somewhat lesser number recommended the disallowance, as optional ingredients in the standards for unenriched wheat products, of individual vitamins and minerals whose addition would suggest to consumers an adequacy for dietary needs not in fact supplied.

The court below characterized this evidence as speculative and conjectural, and held that because there was no evidence that respondent's product had in fact confused or misled anyone, the

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[5] The report of the officer presiding at the hearing enumerates the following varieties disclosed by the testimony:

"Flours, phosphated flours, and self rising flours—
1. One with added vitamin D;
2. One with added calcium;
3. One with added vitamin B_1, nicotinic acid, and calcium [produced by some 23 mills];
4. One with added vitamin B_1, calcium, and iron;
5. One containing wheat germ oil, said to furnish vitamin B_1, vitamin E and riboflavin;
6. One 'long extraction' flour containing vitamin B_1, riboflavin, calcium and iron."

"Farina—
7. One with added vitamin D;
8. One with added vitamin B_1, calcium and iron."

The labels used, and advertising claims made, for those products were not in the record. However, there was testimony that certain of them were sold under such names as "Sunfed", "Vitawhite", "Holwhite".

Administrator's finding as to consumer confusion was without substantial support in the evidence. It thought that, if anything, consumer confusion was more likely to be created, and the interest of consumers harmed, by the sale of farinas conforming to the standard for "enriched farina", whose labels were not required to disclose their ingredients, than by the sale of respondent's product under an accurate and informative label such as that respondent was using.

The Act does not contemplate that courts should thus substitute their own judgment for that of the Administrator. As passed by the House it appears to have provided for a judicial review in which the court could take additional evidence, weigh the evidence, and direct the Administrator "to take such further action as justice may require." H. R. Rep. No. 2139, 75th Cong., 3d Sess., pp. 11-12. But before enactment, the Conference Committee substituted for these provisions those which became § 701 (f) of the Act. While under that section the Administrator's regulations must be supported by findings based upon "substantial evidence" adduced at the hearing, the Administrator's findings as to the facts if based on substantial evidence are conclusive. In explaining these changes the chairman of the House conferees stated on the floor of the House that "there is no purpose that the court shall exercise the functions that belong to the executive or the legislative branches". 83 Cong. Rec., p. 9096. See also H. R. Rep. No. 2716, 75th Cong., 3d Sess., p. 25. Compare *Federal Radio Comm'n* v. *General Electric Co.*, 281 U. S. 464.

The review provisions were patterned after those by which Congress has provided for the review of "quasi-judicial" orders of the Federal Trade Commission and other agencies, which we have many times had occasion to construe.[6] Under such provisions we have repeatedly emphasized the scope that must be allowed to the discretion and informed judgment of an expert administrative body. *Federal Trade Comm'n* v. *Education Society*, 302 U. S. 112, 117; *Gray* v. *Powell*, 314 U. S. 402, 412; *Labor Board* v. *Link Belt Co.*,

[6] The provision adopted by the Conference Committee is one which was proposed as an amendment from the floor of the House by Mr. Mapes, a minority member of the House Committee and one of the House conferees. In proposing it he said that it was "the same as the court review section in the Federal Trade Commission Act with only such changes as are necessary to adapt it to the pending bill", and he referred to "similar" provisions in the Bituminous Coal Commission Act, National Labor Relations Act, Securities Exchange Act, and Federal Communications Act. 83 Cong. Rec., 7892, 7777-8.

311 U. S. 584, 597; *see Federal Communications Commission* v. *Pottsville Broadcasting Co.*, 309 U. S. 134, 141, 144. These considerations are especially appropriate where the review is of regulations of general application adopted by an administrative agency under its rule-making power in carrying out the policy of a statute with whose enforcement it is charged. Compare *Houston* v. *St. Louis Independent Packing Co.*, 249 U. S. 479, 487; *Opp Cotton Mills* v. *Administrator*, 312 U. S. 126, 156. Section 401 calls for the exercise of the "judgment of the Administrator". That judgment, if based on substantial evidence of record, and if within statutory and constitutional limitations, is controlling even though the reviewing court might on the same record have arrived at a different conclusion.

None of the testimony which we have detailed can be said to be speculative or conjectural unless it be the conclusion of numerous witnesses, adopted by the Administrator, that the labeling and marketing of vitamin-enriched foods, not conforming to any standards of identity, tend to confuse and mislead consumers. The exercise of the administrative rule-making power necessarily looks to the future. The statute requires the Administrator to adopt standards of identity which in his judgment "will" promote honesty and fair dealing in the interest of consumers. Acting within his statutory authority he is required to establish standards which will guard against the probable future effects of present trends. Taking into account the evidence of public demand for vitamin-enriched foods, their increasing sale, their variable vitamin composition and dietary value, and the general lack of consumer knowledge of such values, there was sufficient evidence of "rational probative force" (*see Consolidated Edison Co.* v. *National Labor Relations Board*, 305 U. S. 197, 229, 230), to support the Administrator's judgment that, in the absence of appropriate standards of identity, consumer confusion would ensue. *Federal Trade Commission* v. *Raladam Co.*, 283 U. S. 643, 651; *Federal Trade Commission* v. *Raladam Co.*, 316 U. S. 149, 151, 152; *Pacific States Box Co.* v. *White*, 296 U. S. 176, 181. Compare *McLean* v. *Fleming*, 96 U. S. 245, 251, 253-4, 255.

Respondent insists, as the court below held, that the consumer confusion found by the Administrator affords no basis for his conclusion that the standards of identity adopted by the Administrator will promote honesty and fair dealing. But this is tanta-

mount to saying, despite the Administrator's findings to the contrary, either that in the circumstances of this case there could be no such consumer confusion or that the confusion could not be deemed to facilitate unfair dealing contrary to the interest of consumers. For reasons already indicated we think that the evidence of the desire of consumers to purchase vitamin-enriched foods, their general ignorance of the composition and value of the vitamin content of those foods, and their consequent inability to guard against the purchase of products of inferior or unsuitable vitamin content, sufficiently supports the Administrator's conclusions.

We have recognized that purchasers under such conditions are peculiarly susceptible to dishonest and unfair marketing practices. In *United States* v. *Carolene Products Co.*, 304 U. S. 144, 149, 150, we upheld the constitutionality of a statute prohibiting the sale of "filled milk"—a condensed milk product from which the vitamin content had been extracted—although honestly labeled and not in itself deleterious. Decision was rested on the ground that Congress could reasonably conclude that the use of the product as a milk substitute deprives consumers of vitamins requisite for health and "facilitates fraud on the public" by "making fraudulent distribution easy and protection of the consumer difficult."

Both the text and legislative history of the present statute plainly show that its purpose was not confined to a requirement of truthful and informative labeling. False and misleading labeling had been prohibited by the Pure Food and Drug Act of 1906. But it was found that such a prohibition was inadequate to protect the consumer from "economic adulteration", by which less expensive ingredients were substituted, or the proportion of more expensive ingredients diminished, so as to make the product, although not in itself deleterious, inferior to that which the consumer expected to receive when purchasing a product with the name under which it was sold. Sen. Rep. No. 493, 73d Cong., 2d Sess., p. 10; Sen. Rep. No. 361, 74th Cong., 1st Sess., p. 10. The remedy chosen was not a requirement of informative labeling. Rather it was the purpose to authorize the Administrator to promulgate definitions and standards of identity "under which the integrity of food products can be effectively maintained" (H. R. Rep. 2139, 75th Cong., 3d Sess., p. 2; H. R. Rep. 2755, 74th Cong., 2d Sess., p. 4), and to require informative labeling only where no such standard had been promulgated, where the food did not purport to comply with a stand-

ard, or where the regulations permitted optional ingredients and required their mention on the label. §§ 403(g), 403(i); see Sen. Rep. No. 361, 74th Cong., 1st Sess., p. 12; Sen. Rep. No. 493, 73d Cong., 2d Sess., pp. 11-12.

The provisions for standards of identity thus reflect a recognition by Congress of the inability of consumers in some cases to determine, solely on the basis of informative labeling, the relative merits of a variety of products superficially resembling each other.[7] We cannot say that such a standard of identity, designed to eliminate a source of confusion to purchasers—which otherwise would be likely to facilitate unfair dealing and make protection of the consumer difficult—will not "promote honesty and fair dealing" within the meaning of the statute.

Respondent's final and most vigorous attack on the regulations is that they fail to establish reasonable definitions and standards of identity, as § 401 requires, in that they prohibit the marketing, under the name "farina", of a wholesome and honestly labeled product consisting of farina with vitamin D added, and that they prevent the addition of vitamin D to products marketed as "enriched farina" unless accompanied by the other prescribed vitamin ingredients which do not co-act with or have any dietary relationship to vitamin D. Stated in another form, the argument is that it is unreasonable to prohibit the addition of farina to vitamin D as an optional ingredient while permitting its addition as an optional ingredient to enriched farina, to the detriment of respondent's business.

The standards of reasonableness to which the Administrator's action must conform are to be found in the terms of the Act construed and applied in the light of its purpose. Its declared purpose is the administrative promulgation of standards of both iden-

[7] A Message of the President, dated March 22, 1935, urging passage of the bill and particularly of the standard of identity provision, pointed out that "The various qualities of goods require a kind of discrimination which is not at the command of consumers. They are likely to confuse outward appearances with inward integrity. In such a situation as has grown up through our rising level of living and our multiplication of goods, consumers are prevented from choosing intelligently and producers are handicapped in any attempt to maintain higher standards." H. R. Rep. No. 2755, 74th Cong., 2d Sess., pp. 1-2.

The Chairman of the Food and Drug Administration testified before the Senate Committee that the provision for standards of identity which would reflect "the expectation of the buyer" was "one of the most important provisions of the Act." Hearings before a Subcommittee of the Senate Committee on Commerce on S. 1944, Dec. 7 and 8, 1933, pp. 35, 36.

tity and quality in the interest of consumers. Those standards are to be prescribed and applied, so far as is practicable, to food under its common or usual name, and the regulations adopted after a hearing must have the support of substantial evidence. We must reject at the outset the argument earnestly pressed upon us that the statute does not contemplate a regulation excluding a wholesome and beneficial ingredient from the definition and standard of identity of a food. The statutory purpose to fix a definition of identity of an article of food sold under its common or usual name would be defeated if producers were free to add ingredients, however wholesome, which are not within the definition. As we have seen, the legislative history of the statute manifests the purpose of Congress to substitute, for informative labeling, standards of identity of a food, sold under a common or usual name, so as to give to consumers who purchase it under that name assurance that they will get what they may reasonably expect to receive. In many instances, like the present, that purpose could be achieved only if the definition of identity specified the number, names and proportions of ingredients, however wholesome other combinations might be. The statute accomplished that purpose by authorizing the Administrator to adopt a definition of identity by prescribing some ingredients, including some which are optional, and excluding others, and by requiring the designation on the label of the optional ingredients permitted.[8]

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[8] The standard of identity provision was repeatedly stated in the Committee reports to have been patterned on the Butter Standards Act of 1923, 42 Stat. 1500. Sen. Rep. No. 361, 74th Cong., 1st Sess., p. 10; Sen. Rep. No. 646, 74th Cong., 1st Sess., p. 4; Sen. Rep. No. 493, 73d Cong., 2nd Sess., p. 10; H. R. Rep. No. 2139, 75th Cong., 3rd Sess., p. 5. That Act was entitled "An Act to define butter and provide a standard therefor", and established a legislative definition and standard for butter. The Chairman of the House Committee which reported it said "The only things you can put into [butter] are salt, casein, the butter fat, and water. That is what the definition provides." Hearings, House Committee on Agriculture on H. R. 12053; 67th Cong., 2nd Sess., p. 25; see also H. R. Rep. No. 1141, 67th Cong., 2nd Sess., p. 4.

Also referred to as models for the standards to be promulgated under the present act were the advisory standards then being promulgated by the Pure Food and Drug Administration under the authority given by the Appropriation Act of June 3, 1902, 32 Stat. 286, 296, and subsequent acts. Hearing before a Subcommittee of the Senate Committee on Commerce on S. 1944, Dec. 7 and 8, 1933, p. 36. (Statement of Walter B. Campbell, Chief of Food and Drug Administration; Dept. of Agriculture.) The announcements promulgating these standards stated that they were "so framed as to exclude substances not mentioned in the definition." E. g., Dept. of Agriculture, Food and Drug Administration, Service and Regulatory Announcement No. 2, Revision 4 (1933) p. 1; *id.*, Rev. 8 (1936) p. 1.

Since the definition of identity of a vitamin-treated food, marketed under its common or usual name, involves the inclusion of some vitamin ingredients and the exclusion of others, the Administrator necessarily has a large range of choice in determining what may be included and what excluded. It is not necessarily a valid objection to his choice that another could reasonably have been made. The judicial is not to be substituted for the legislative judgment. It is enough that the Administrator has acted within the statutory bounds of his authority, and that his choice among possible alternative standards adapted to the statutory end is one which a rational person could have made. *Houston v. St. Louis Independent Packing Co.*, *supra*, 487.

The evidence discloses that it is well known that the milling process for producing flours and farinas removes from the wheat a substantial part of its health-giving vitamin contents, which are concededly essential to the maintenance of health, and that many consumers desire to purchase wheat products which have been enriched by the restoration of some of the original vitamin content of the wheat. In fixing definitions and standards of identity in conformity with the statutory purpose the Administrator was thus confronted with two related problems. One was the choice of a standard which would appropriately identify unenriched wheat products which had long been on the market. The other was the selection of a standard for enriched wheat products which would both assure to consumers of vitamin-enriched products some of the benefits to health which they sought, and protect them from exploitation through the marketing of vitamin-enriched foods of whose dietary value they were ignorant. In finding the solution the Administrator could take into account the facts that whole wheat is a natural and common source of the valuable dietary ingredients which he prescribed for enriched farina; that wheat is not a source of vitamin D; that milk, a common article of diet, is a satisfactory source of an assimilable form of calcium; that the principal function of vitamin D is to aid in the metabolism of calcium; and that milk enriched with vitamin D was already on the market.

We cannot say that the Administrator made an unreasonable choice of standards when he adopted one which defined the familiar farina of commerce without permitting addition of vitamin enrichment, and at the same time prescribed for "enriched farina"

the restoration of those vitamins which had been removed from the whole wheat by milling, and allowed the optional addition of vitamin D, commonly found in milk but not present in wheat. Consumers who buy farina will have no reason to believe that it is enriched. Those who buy enriched farina are assured of receiving a wheat product containing those vitamins naturally present in wheat, and, if so stated on the label, an additional vitamin D, not found in wheat.

Respondent speaks of the high cost of vitamin B_1 ($700 per pound), but there was evidence that the cost of adding to flour the minute quantities of the four ingredients required for enriched farina would be about 75 cents per barrel, and respondent concedes that the cost to it may be but a fraction of a cent per pound. The record is otherwise silent as to the probable effect of the increased cost on the marketing of respondent's product. On this record it does not appear that the increased cost has any substantial bearing on the reasonableness of the regulation.

We conclude that the Administrator did not depart from statutory requirements in choosing these standards of identity for the purpose of promoting fair dealing in the interest of consumers, that the standards which he selected are adapted to that end, and that they are adequately supported by findings and evidence.

Reversed.

Mr. Justice MURPHY and Mr. Justice RUTLEDGE took no part in the consideration or decision of this case.

Mr. Justice ROBERTS is of opinion that the judgment should be affirmed for the reasons stated by the Circuit Court of Appeals, 129 F. 2d 76.

A true copy.

Test:

Clerk, Supreme Court, U. S.